A Comparison Study of Health Benefits and Cost Savings of Diabetes Medications Used To Treat Type II Diabetes in the State of Georgia, United States of America

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By

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Abstract

Actionable research, at a doctoral level, allows personnel to utilize personal experiences within the *organization* to explore the possibility to manifest change through collaborative efforts of internal and external stakeholders within the *industry* (Coghlan and Brannick, 2010).

Background:

The practice-based problem for this actionable research is as follows: In the United States, branded medications used to treat type II diabetes are more expensive than generic medications. The literature lacks sufficient evidence to support the healthcare provider's decision to order a more expensive product to treat this chronic disease, type II diabetes as opposed to a less expensive product.

Aim / Objectives:

The process of *action learning* addressed the aim and objectives for this study. To begin with, the survey conducted in this study was to address the prevalence and impact of type II diabetes in the state of Georgia, USA via uncovering the direct and indirect costs associated with this chronic disease. Using this demographical and geographical diverse population in the state of Georgia, inferences about the health benefits and cost-savings of diabetes medications used to treat type II diabetes created the aim of the study by properly characterizing the type II diabetes population in Georgia.

The objective of the study was to utilize the actionable knowledge gained from the study to create a data-driven document that can be executed in the decision making process of treating type II diabetes. This actionable knowledge led to the creation of a *new* document which involves the decision-making process of the healthcare professional. This document allows the rationality of integrating factors that are associated with the standards of care when choosing a

medication to treat type II diabetes such as efficacy and safety ~ instead of simply the cost of the medication at the pharmacy counter.

Methodology:

The impact of type II diabetes on the state of Georgia was determined by using a patient-centered approach. Upon gathering data, the process of micro-costing was implemented to estimate the cost of treatment(s) and complications related to type II diabetes. Generic and brand name medication pricing were determined by referencing GoodRx.com and Cost Helpers, Inc. An analysis of variance was obtained using inferential and descriptive statistics to compute the direct and indirect costs associated with the treatment of type II diabetes.

Results:

Upon completion of the comparison of health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, USA, the results were not statistically significant. However, the literature review revealed a number of studies that not only resulted in a statistical significance but a clinical significance as well (Saydah et al, 2004; Carnethon et al, 2010; Loeppke et al, 2009; Fitch et al., 2017). In fact, this action learning research revealed the health benefits of the branded medications outweighed the health benefits of the generic medications. The patient-reported data of less complications and hospitalizations was associated with the branded, more expensive products. This is important because a reduction in diabetes-related complications results in an overall reduction in the cost to treat type II diabetes in the United States (Fitch et al., 2017).

Conclusions:

The two theoretical frameworks used for this study included the following: Choo's *Knowing Organization* was the foundation used to enhance the knowledge of this writer regarding the

prevalence and impact of type II diabetes on the state of Georgia, USA. The completion of the study created actionable knowledge, a depiction of direct and indirect costs associated with type II diabetes. The itemization of these costs indicated that cardiovascular related complications were responsible for the majority of the expenses related to type II diabetes. Simon's *Bounded Theory of Rationality* was the foundation used to create a modified version of a *Pay for Performance* model. This model was used to create a document to address the long-term complications associated with type II diabetes, namely cardiovascular related complications. The implementation of this tool creates a clinically justifiable reason to prescribe a product for the type II diabetes. This rationale is based on efficacy and safety ~ not simply the nominal cost of the medication. The underlying concept of this tool is to strengthen the accountability efforts of the pharmaceutical company to produce value-based results for those patients adhering to the prescribed regimen.

List of Abbreviations

AACE	American Association of Clinical Endocrinologists
AAFP	American Academy of Family Physicians
ACE	American College of Endocrinology
ADA	American Diabetes Association
AGI	Alpha-glucosidase inhibitors
ASCVD	Atherosclerotic cardiovascular disease
BMI	Body Mass Index
CCK	Cholecystokinin
CV	Cardiovascular
DM	Diabetes Mellitus
GLP1	Glucagon-like Peptide 1
HDL	High-density lipoprotein
LAOA	Latent Autoimmune Diabetes
LDL	Low-density lipoprotein
MOA	Mechanism of Action
OXM	Oxyntomodulin
PSC	Pharmaceutical Sales Consultant
PYY	Peptide Tyrosine Tyrosine
SU	Sulfonylurea
TZD	Thiazolidinedione

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I am proud to be a graduate of one of the most prestigious institutions of higher learning in the world – the University of Liverpool. I would like to acknowledge my professors at the University of Liverpool, especially Dr. Hefin Rowlands and Dr. Jason Macvaugh. I would also like to acknowledge my husband, Dr. Kevin Henderson and my family, without their support and guidance, obtaining this life-long goal would not have been possible. Their unconditional love has fueled my momentum throughout these years. Last, but certainly not least, I would like to thank those persons living with type II diabetes who participated in this study. The data gathered from these participants shall provide much needed insight into the treatment of type II diabetes. I sincerely hope that the results of this study will motivate change in the way in which diabetes is assessed and managed in the United States of America. Through advancements in healthcare and education, together we can improve the well-being of all persons affected by type II diabetes. I would like to extend my hand in prayer to all of those persons, albeit mentioned or not, who were instrumental in supporting my efforts to achieve this doctorate degree.

Merci a` mon Seigneur et Sauveur Je`sus-Christ de m`avoir beni`

Je peux faire toutes choses en Christ qui me renforcent. Philippiens 4:13

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Operational Definitions

Agent : A term used synonymously with a pharmaceutical drug - medication

Antidiabetic Agents: Medications used to treat type II diabetes.

Atherosclerotic cardiovascular disease (ASCVD): A condition caused by plaque accumulation on arterial walls; clogged arteries; also known as CHD (Coronary heart disease)

Bioequivalence: A term indicating a comparison of two pharmacokinetic preparations deemed identical.

Branded Medication: Manufactured medication named and developed by a pharmaceutical company for the purpose of marketing and advertising. The term is synonymous with "non-generic".

Cardio-metabolic Risk Factors: Factors that increase the chances of one damaging one's blood vessels and or heart. These risk factors may include obesity, high LDL (bad cholesterol), high blood fat (triglycerides), low HDL (good cholesterol), high blood pressure and /or insulin resistance.

Cloud computing: This term is used when services completed within the integrated technology systems, i.e. computer, is stored for future retrieval.

Cost Savings: Savings incurred due to decreased healthcare related spending.

Dialysis (Kidney Dialysis) (Hemodialysis): A process whereby waste products are eliminated from the blood by a hemodialysis machine due to insufficient renal abilities. The cleansed blood is returned to the body upon completion of the filtration process.

Direct Costs: Costs incurred to treat the diabetes relating the pharmaceutical treatments, tests, procedures, inpatient care, outpatient care and durable medical equipment.

Endocrinopathies: Diseases associated with the endocrine gland such as diabetes, hyperthyroidism and hypothyroidism.

Exocrine Pancreas: The organ called the pancreas contains exocrine glands the create enzymes which are crucial to the breakdown of proteins, carbohydrates and fats.

Exogenous: Pertaining to an outside factor - Exogenous insulin administered via an injection as opposed to endogenous insulin which is physiologically secreted from the pancreas.

Generic medication: A medication that is comparable to a brand named drug. The product is sold at a lower price because it is no longer patent-protected. The term is synonymously as "non-branded".

Gold Standard: The finest and most reliable example of the referenced subject matter

Health Benefits: A term indicating a reduction in risk factors and complications associated with diabetes secondary to adequate blood glucose control.

Hemochromatosis: A genetic disorder characterized by iron salts being present in the tissues of the body. This may lead to hepatic damage, blood sugar abnormalities and skin discolorations (a tannish color).

Hemoglobin A1C (A1C): A blood test used to identify the average blood glucose level of a human for the previous 3 months.

Hepatic: Pertaining to the liver

Hyperglycemia: Elevated blood glucose level

Hyperthyroidism: Over activity of the thyroid gland leading to an increased metabolism as well as an elevated heart rate

Hypoglycemia: Low blood glucose level

Hypothyroidism: An abnormally low secretion of the thyroid hormone from the thyroid gland resulting in stunted growth and delayed development in both children and adults

Immune – mediated diabetes: A disorder causing the body to destroy its own cells in the pancreas that is responsible for creating the life-saving hormone, insulin

Incretins: A group of metabolic hormones in the human body causes a decrease in blood glucose levels**.**

Indirect Costs: Non-medical costs associated diabetes such as an absence from work or decrease earning abilities due to illness.

Insulin: A hormone that regulates the transport of glucose into the body's cell

Neoplasia: Abnormal cellular growth of tissue – occurring anywhere in the body

Nocturnal Hypoglycemia: Blood sugar level less than 70mg/dl during the night while sleeping

Obesity: A medical condition identified by a BMI of 30kg/m2

Pancreatitis: An inflammation of the pancreas, which is flat gland located behind the stomach.

Satiety: A state of a feeling of fullness upon consumption of a meal

Tiered Medication Formulary System: Medications categorized within a formulary system clustered into groups designated by cost. For instance, tier one usually consists of generic mediations, tier two usually consists of preferred branded mediations and tier three are non-preferred (often for specialized conditions) branded medications. The pricing of these medications is based on the assigned tier. Tier one is usually the least expensive and tier three is the most expensive product(s).

Thematic Research: A type of research, usually qualitative, that consists of an analysis of patterns identified within the data. Themes in the data are revealed upon completion of the analysis.

Type I (one) Diabetes: A form of diabetes whereas the pancreas secretes very little to no insulin - also known as juvenile onset diabetes.

Type 1.5 Diabetes: A form of diabetes in the adult population that do not immediately require insulin for treatment and are usually not overweight. These personas have little or no resistance to insulin - also known as Latent Autoimmune Diabetes in Adults.

Type II (two) Diabetes: A form of diabetes whereas the pancreas either resists the effects of insulin or does not secrete enough insulin to maintain a normal blood glucose level

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CHAPTER 1: INTRODUCTION

1.1 Introduction

This action learning based study is an investigation into the *true* cost of treating the chronic disease, type II diabetes. It is a comparison study of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. As the healthcare industry evolves, healthcare providers find data driven studies, such as this one, beneficial in the decision-making process regarding disease management (Lundqvist, Anderson, and Carlson, 2016). The literature confirms that not only is the pharmaceutical industry evolving but so are the treatment modalities to treat chronic diseases such as diabetes (American Diabetes Association, 2018; Wild, Roglic, Green, Sicree and Kang, 2004). In fact, one of the greatest challenges in healthcare is the cost of medications to treat chronic diseases such as type II diabetes (American Diabetes Association, 2018). Due to the concepts surrounding value based medicine and cost profiling, healthcare providers are often forced to choose the cheaper / generic medications to treat diabetes. In the United States, the healthcare providers are practicing medicine via a tiered formulary system for healthcare choices including prescription medications (Kahn & Anderson, 2009).

1.2 Context of Study

For the past nineteen years, I have been a pharmaceutical sales consultant for NovoNordisk Pharmaceuticals. A primary concern for my company includes creating a productive sales force because the healthcare industry is changing and the medical staff no longer dictates the treatment regimen. In other words, the managed care system

is often the deciding factor in the treatment regimen chosen for the patient. Therefore, the sales team has a tremendous challenge persuading the healthcare provider to order a branded medication that is not covered via insurance. If the medication is too expensive and the healthcare provider is penalized for choosing that medication, needless to say, the less expensive medication is usually chosen for the patient, albeit the more efficacious choice or not. The information gathered and the analysis performed in this action learning based study is helpful to the pharmaceutical sales consultant to communicate effectively with the business-minded stakeholders within the pharmaceutical industry.

As a tenured pharmaceutical sales consultant, this is a work place problem that continues to intensify not only at an organizational level but at an industry level as well (Apovian, 2013; Herman, 2011; Hussey, Sorbero and Mehrotra, 2009). According to Gavagan et al. (2010), not only are the healthcare providers penalized by managed care companies for prescribing the more expensive medication but they are incentivized for prescribing the cheaper/generic medications. To further explain, the cheaper / generic medications are generally at a lower tier and cost less than the brand name medications. The generic medications used to treat type II diabetes are efficacious to a point; however, their usage may exacerbate some significant health-related issues such as weight gain and hypoglycemia – which ultimately can affect one's quality of life (DiBonaventure et al., 2011; Cawley et al., 2008). The newer, more expensive brand name medications used to treat type II diabetes are generally on a higher tier and cost more but can be more efficacious than generic medications (Asnani, Richard, Desouza & Fonseca, 2003; Inzucchi et al.,2012; American

Diabetes Association, 2019). These medications are often associated with health benefits such as weight neutrality or even weight loss (Jacob et al., 2007). According to Caro et al. (2002), when treating type II diabetes, the healthcare provider is expected to consider the nominal cost as well as the untoward effects of the prescribed treatment regimen. Researching the *true* cost of cheap generic medicines will demonstrate, in some instances, that a newer more expensive brand name medication can be a better healthcare value than lower cost generic medications (Conner et al., 2008). In fact, the concept of value- based healthcare is based on this premise (Damberg et al., 2009). This doctoral thesis will enable healthcare professionals to view the treatment of type II diabetes and its complications through a broader lens of *cost* and not just the monetary cost of medications used to treat this chronic illness. The business aspect of this literary document has been revealed as the overall value of the medications used to treat type II diabetes in the United States is disclosed and demonstrated through theory, decision-making theory (Simon, 1990).

1.3 Problem Statement

The pharmaceutical sales industry is a business. If the sales force is unable to generate sales due to managed care constraints, the company is not able to get a return on its investment. For the past three years, NovoNordisk , as many other pharmaceutical companies with sales forces in the United States, have experienced "lay-offs" resulting in jobs lost due to financial constraints. The United States of America is undergoing some unprecedented changes in healthcare (American Diabetes Association, 2016; Hussey, Mulcahy, Schnyeer, & Schneider, 2012). These

changes have been progressing for many years and are affecting the national debt, the stakeholders within the healthcare arena (healthcare providers, managed care, pharmacists, etc.), the pharmaceutical industry as well as the consumers (King et al., 1998; American Diabetes Association, 2019). Type II diabetes is a chronic condition that affects both men and women in America. However, Carnethon et al. (2010) reveal that elderly patients, poor socioeconomic portions of the community and minorities are impacted far more than other populations. Diabetes is a major contributor to the national debt (American Diabetes Association, 2019; King et al., 1998; Boyle et al., 2010). Diabetes and the treatment modalities as well as its complications are costly components within this equation (American Diabetes Association, 2019; Boyle et al., 2010; King et al., 1998; Caro et al, 2002). Even though this chronic disorder is costly and has reached epidemic proportions, it is also reportedly preventable (Brown et al., 1999). The surmounting debt surrounding diabetes is placing a tremendous burden on not only the national budget but the state of Georgia's budget as well (King et al., 1998; ADA, 2013). The managed care industry restricts certain medications to certain patients in an attempt to "save money" (Luce, 2005). This dissertation shall *compare the health benefits and cost-savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America* in an effort to provide a solution to the problem in generating prescriptions in a compromised managed market. This comparison study is a type of health impact assessment designed to identify value association with treatment regimen(s) used to treat the chronic disease, type II diabetes (Harris-Roxas, Villani, Bond, Cave, Divall, Furu, et al., 2012). From an organizational management

perspective, the actionable knowledge generated from a health impact assessment, such as this study, is transferrable (Das, Everett, Birtcher et al., 2018; Friedhoff, 2009). Transferrable, in an effort to address complex issues albeit within an organization or an industry. This complex issue of cost surrounding chronic illnesses is an organizational issue within our pharmaceutical company as well as within the industry (Dietz, Belay, Bradley et al., 2017). Providing a viable solution to addressing the *true* cost associated with chronic diseases, such as type II diabetes affects the triple bottom line of the (pharmaceutical) company and ultimately the overall well-being of the (pharmaceutical) industry (Pava, 2007).

1.4 Aim / Objectives

Cost is a leading factor in the decision-making process of prescribing medications used to treat chronic illnesses in the United States of America, such as type II diabetes (Narayan et al., 2006). The aim for this study was to conduct a comparison study using a demographical and geographical diverse population within the state of Georgia to make inferences about the health benefits and cost-savings of diabetes medications used to treat type II diabetes.

The objectives of the study were as follows:

- identify the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia through evidence - based data

- transition this evidence – based data into actionable knowledge by creating an algorithm to address the work - place problem concerning sales lost due to managed care restriction at the healthcare provider level of treatment.

According to the Annual Report of America's Health Rankings (2017) Georgia, the geographical workplace of the investigator ranks amongst the highest in individuals diagnosed with diabetes at 12.1% (America's Health Rankings, 2017). The description of the correlation of direct/indirect expenditures, individual demographic traits, pharmacological agent(s), diabetes related complications and comorbidities associated with individuals diagnosed with type II diabetes has been revealed. These variables are being considered to determine the overall value of the medications used to treat type II diabetes in the state of Georgia, United States of America as well as the overall complications associated with this chronic disease.

1.5 Significance of the Study

The significance of creating this knowledge is to serve as a component to develop a model, that when implemented, will make a difference within my place of employment, a pharmaceutical organization, as well as the pharmaceutical industry. As an investigator, I am able to discuss the comparison of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia. As this data was obtained, a monetary value was associated with not only the disorder but the complications associated with diabetes as well. Reviewing the raw data coupled with an extensive literature review and the opportunity to create a viable

option for my sales force in an effort to "prevent another company layoff" truly signifies a trait of a leader. As a leader in the industry of pharmaceutical sales, I recognize that this dilemma of cost associated with diabetes has caused a rippling effect within the healthcare industry. The pharmaceutical industry is often labeled a part of the problem (Friedhoff, 2009). However, as an investigator, this study will allow us to be a part of the solution as the "value" component of the equation, as it relates to treatment, will be assessed.

Performing this health impact assessment allowed this writer to examine the changes incorporated into healthcare reform and its relationship to the escalating cost of healthcare in America. Creating viable options to deal effectively with managed care is truly the key to addressing this action learning based problem. To further elaborate, healthcare reform affects how the providers choose treatment modalities for the patients (Kahn & Anderson, 2009). As discussed earlier, in the United States, a tiered copay system is used to decide on the purchasing price of medications (Austvoll – Dahlgren et al., 2008). In Georgia, the older medications used to treat diabetes are often generic and are tiered at lower co-pays than the newer branded agents. Each of the aforementioned stakeholders within the pharmaceutical industry, have interests that are indeed *vested* in the medications chosen for treatment (Curtin et al., 2006). Implementing a study designed to examine the benefits versus cost savings of the diabetes medications used in Georgia is a clinically relevant approach that can be used to significantly impact the decision-making process of those utilizing the algorithm for diabetes management (Aron et al. 2008; Austvoll – Dahlgren et al., 2008). Those decision-makers utilizing the algorithm for diabetes management in the

United States will be able to use the quantifiable evidence from this study to identify the *true* cost (indirect and direct) of diabetes medications used to treat type II diabetes in the state of Georgia (Boyle et al., 2010; American Diabetes Association, 2013). The theoretical concepts of Herbert Simon, *bounded rationality* – which will be fully explained in Chapter 2 - supports the algorithmic procedures to strategize in an effort to solve problems within an organization (Barros, 2010; Simon, 1990). Furthermore, Choo (2002) reveals a framework ideal for use in organizations aiming to expand upon knowledge in order to create advancements within the industry. Establishing a '*knowing organization'*, which will also be fully explained in Chapter 2, can be created effortlessly with stakeholder preparation and participation (Choo & Johnson, 2003). Implementing the concepts within the *knowing organization* will be beneficial as the decision-makers create a viable solution to address managed care constraints associated with the generation of a prescription for branded products used to treat type II diabetes.

1.6 Summary

The prevalence of type II diabetes continues to rise, regardless of the number of new treatment modalities manufactured for the market **(**American Diabetes Association, 2013; Dybicz et al. 2011; King et al., 1998). As the national debt rises in the United States of America, the healthcare community recognizes the effects on the various entities involved such as the healthcare providers, managed care providers, pharmaceutical industry and most importantly, the consumers. Chronic disorders, such as type II diabetes, have created an economic burden on the national economy of the United States (Cheng et al., 2013; Boyle et al., 2010; Poisal et al.,

2007). This economic burden has forced the administration of the United States government to review these expensive health-related issues and create a plan of action. This plan of action has been identified as the new 'healthcare reform' (Wild et al., 2004; Kahn & Anderson, 2009). This plan of action addresses many issues; however, the involvement of the American people allows one to view it from a public health perspective. According to Eggleston et al., (2009), this will often require support from the state, federal or international level. Implementing this study at the state level will allow the policy-makers to heighten recognition for the need to view the indirect and well as direct cost for the treatments used for type II diabetes.

Educating the stakeholders about the correlation of health benefits and medication costs have become increasingly important in addressing the escalating rate of healthcare expenditure in the United States (Kantarjian et al., 2013). The survey conducted in this study has been designed to identify the comparison of the health benefits and cost-savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. It was conducted solely for the purpose of characterizing the type II diabetic population in Georgia. The population targeted for this study was type II diabetic patients who are actively involved in diabetes education classes via diabetes support group meetings throughout the state. The significance of this work place problem is that failure to address the interrelated issues of cost-savings and health benefits of pharmaceutical agents used to treat diabetes could be detrimental not only for the economy but for the person diagnosed with type II diabetes as well (Caro et al., 2002; Ogden et al., 2012; Boyle et al., 2010).

The questionnaire distributed to the subjects was designed to identify subject characteristics (i.e., age, sex and race), duration of illness, pharmacological agents used to treat diabetes, diabetic complications and comorbidities – including weight gain, stroke, heart attack, blindness, dialysis and amputation. An assessment was conducted to determine time loss from work as well as medication / treatment regimen satisfaction. The study results were statistically calculated based on the findings and the limitations of the study.

The theoretical framework of creating a "*knowing organization*" was implemented to address this workplace problem of knowing the specifics relating to the local population plagued with this chronic disease. These concepts of goal-setting through cycles of sense making, knowledge creation and decision making, allow the stakeholders to view a return on investment with a consumer-centered approach (Choo, 1998). As the actionable knowledge is revealed, the theoretical framework of *bounded rationality* was implemented to support the decision- making process to create a model to implement as a solution to the workplace problem (Velupilai, 2010; Barros, 2010).

This doctoral dissertation consists of seven chapters. Chapter 1 has been explained in its entirety in the aforementioned paragraphs. Chapter 2 is a comprehensive literature review for this study. In this section, the following areas of study were reviewed: the management related perspectives of the study, the actual business problem, two theoretical frameworks, diabetes management and its relationship to goal development. Hypotheses are identified in the latter portion of this section. Chapter 3 depicts the research methodology for this study. The general

approach implemented to carry out this study has been reviewed in the research setting, population sampling, ethical considerations, research design, research instrument, data collection and recording as well as the analysis of the data. Chapter 4 identified the story of cycles of action within the study, a vivid reflection of the demographics of the sample population and the sense-making of the results discovered within the group. Chapter 5 discloses an extensive evaluation of the outcomes of the study. The research outcomes have been reviewed in its entirety. A full discussion of the cost savings and health benefits of these findings are revealed as well. The FDA approved pharmacological treatments used to treat type II diabetes in the United States of America, monotherapy as well as combination therapy, has been reviewed. A summation of the direct and indirect cost of the treatment regimen(s) has been statistically analyzed and the hypotheses tested accordingly. Chapter 6 depicts a conclusion and an overall summation of this study. The final chapter, chapter 7, related the findings to the actionable knowledge and practice of the research. The limitations, recommendations for further research as well as my reflections on lessons learned throughout this academic process has been revealed in the latter section of chapter 7.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Chapter 2 represents an extensive literature review into the topic of evaluating the health benefits and cost savings of medications used to treat type II diabetes in the state of Georgia, United States. In this data driven study, areas of interest include the management related perspective of the study, pathophysiology associated with the disease process, epidemiological cost factors, pharmacological agents used to treat type II diabetes, diabetes management development as well as diabetes management and cost effectiveness. In this action learning based research, work place relativity is of utmost importance as well; therefore, various aspects of these components are reviewed. These areas of interest include an extensive review of workplace relativity, the action learner relevance and profile, evaluating this process via scientific thinking for both the investigator and the stakeholder within the pharmaceutical industry. Lastly, this study is a form of assessment – a health impact assessment. The significance of health impact assessments shall be reviewed in its entirety.

2.2 Management related perspective of the study:

The management perspective of this study stems from the high cost of prescription medications to the stakeholders within the industry (American public, government, employers, health insurance companies, managed care organizations, etc.) and the consequences associated with such pricing. The literature review in section 2.2.1 reveals the models created for value based healthcare which were developed by the U.S. Department of Health and Human Services (HHS), These models were created

in an effort to correlate a strategy whereas the healthcare provider would treat the consumer as per established medical guidelines while being mindful of the cost. Treating the consumer with quality care while being as frugal as possible seems to be the goal for each of the value based healthcare models. Goal achievement is identified via actual cost savings (Chung, Palaniappan, Wong, Rubin, and Luft (2010); Damberg, Shortell, Raube, Gillies, Rittenhouse, McCurdy, Casalino and Adams (2010)). These value based healthcare programs were created to establish accountability amongst the healthcare industry. There are three major value based healthcare models implemented throughout the managed care market in the United States of America ~ *Pay for Performance, Accountable Care Organizations and Bundled Payments.*

2.2.1 Value Based Healthcare Models

- **Pay for performance (P4P):** In this particular model, the healthcare provider is either incentivized with bonuses or penalized via reduced payments, depending on patient outcomes. These patient outcomes are evaluated using preset quality measures. These preset quality measures are established by the payer i.e., managed care organization(s).
- **Accountability care organization (ACO):** An ACO is more of a voluntary team effort. In this type of model, every healthcare provider within the system agrees to be held accountable for not only the quality of care but the total "bottom line" cost of treating the consumer. In an ACO, performance regarding quality care and (the consumer) meeting clinical metrics with

prescribed treatment regimen(s) are linked to optimal reimbursement rates. With this agreement, the providers are aware of the risks. If an audit is completed and the group does well i.e. the consumers have blood pressures, blood sugars, BMI's and cholesterol levels in range and the goal has been accomplished within "budget" then the group is incentivized with a bonus. This tactic is identified as *improved care delivery*. The managed care organization shares the savings with the ACO. On the other hand, if the metrics are not met, albeit through the physical assessments or the budget, then the ACO is penalized via less reimbursement for the care rendered.

- **Bundled payments:** This form of value-based healthcare is usually associated with physicians and facilities associated with home health care, outpatient surgical centers, mental health facilities, long term skill care, nursing homes, oncology / hospice, or ambulatory care centers. The healthcare facility/ provider is compensated a set nominal amount for each episode of an illness ~ time is a factor. The following scenarios will further explain: if a contract has been created for Mr. John Doe and a nominal fee of four thousand dollars has been provided to XYZ mental health facility for an admission of a chronic disorder such as schizophrenia then the facility is compensated that amount. However, if Mr. John Doe should have an exacerbation of his illness and require readmission within thirty days of discharge from the facility then the facility will not receive compensation for the care rendered upon this readmission. Scenario # 2: If a contract has been implemented for a broken limb for an outpatient surgical center and a nominal

fee of ten thousand dollars has been provided to XYZ ambulatory surgical center for a broken femur for Mrs. Jane Doe then it is granted. However, if the consumer reinjures that affected area within thirty days and requires readmission, the facility will not receive compensation for treating the new episode.

2.2.2 Incentives

The literature review reveals that the value based healthcare programs incentivize the healthcare providers and facilities in a number of ways. Shen (2003) contends that the incentives may include not only bonuses to the medical staff but higher reimbursement rates within the fee schedule, preferred status on the insurance plan (meaning less copay for the consumer) even on-line sign up with the managed care provider. It is customary to implement one or more of these incentives simultaneously (Chien, Eastrman and Rosenthal, 2012). Chronic diseases place such a heavy burden on the healthcare system and managed care has established a plan of using quality measures and incentives to address the issue(s). The literature reveals an abundance of feedback regarding performance of quality measures as it relates to value based healthcare programs; however, studies regarding the return on investment from a clinical standpoint of such programs are limited ~ especially with chronic disorders such as diabetes. Chen et al. (2010) conducted a longitudinal study assessing the return on investment for a pay-for-performance program designed to increase quality care and decrease hospitalization rates among patients with diabetes. The findings concluded that the consumer who was assigned to the pay-for-

performance healthcare provider was more likely to receive quality care and less likely to be hospitalized. However, the study revealed that there was no significant difference in the quality of care received from the "newly appointed" pay-for-performance provider and the non-participating pay-for-performance provider. Selection bias was identified as a potential flaw in this study. Curtin, Beckman, Pankow ,Milillo and Green (2006) conducted a study on a program with a five year partnership between a health plan and an independent practice association. The performance was based on quality, consumer satisfaction and efficacy of the healthcare provider. The program reported a positive return on investment 1.6:1 within three (3) years of the study and 2:5.1 within (4) years of the study.

2.2.3 Implications of value based healthcare

Fendrick and Chernew (2006) contend that the value based healthcare programs were designed to specifically address quality of care and cost containment. In fact, these programs focus on initiatives surrounding disease management and quality of care. These programs make certain that quality measures are identified in the goal setting process and proper tracking is crucial. Even though proper tools are identified for assessment and medications are provided, the higher priced medications with the safer side effect profile are often not chosen. According to Fendrick and Chernew (2006), when a consumer is required to pay more for their care, they have a tendency to buy less, even for management of a chronic disease.

If a provider has been penalized for prescribing an expensive medication to treat a chronic disease, such as diabetes, he/she may *not* be on the preferred list of healthcare

providers. When the consumer does visit this (out of network) provider, the copay is more expensive and often times they are less likely to purchase an expensive medication. When the healthcare provider is not on the preferred list, many opt to simply choose another healthcare provider. These are consequences associated with value-based healthcare.

When viewed in isolation, the direct cost of branded prescription medications can seem quite expensive. However, according to Herman (2011), a broader view of the cost of medications is needed in order to treat the consumer. According to Zhuo, Zhang and Hoerger (2013) and Herman (2011), the following must be considered when choosing medications for treating various conditions: drug related complications, avoided inpatient hospitalizations including emergency department visits and overall efficacy and safety of the medication chosen. These viewpoints can provide greater clarity as it relates to data based evidence in the assessment of the true *cost* of medication therapy.

2.2.4 Direct and indirect cost associated with type II diabetes

This study examined the direct and indirect cost of medications used to treat type II diabetes using a broader view of the actual cost of these medications. A process known as Budget Impact Analysis (BIA) along with Cost-Effective Analysis (CEA) are used to determine the true cost of medications used to treat type II diabetes in specific clinical situations. The literature reveals that every twenty-one seconds a person is diagnosed with diabetes in the United States (American Diabetes Association, 2017). According to the American Diabetes Association (2013), the

direct medical cost to the U.S. economy related to diabetes in 2012 was estimated to be 176 billion dollars.

The categorization of the cost used to treat diabetes in 2012 (American Diabetes Association, 2013) is listed in Chart A below:

Cost	**Direct medical**	**Meds to treat diabetes**	**Inpatient hospital**	**Meds to treat diabetes complications**
2012	**$176 billion**	**$21.1 billion**	**$75.7 billion**	**$31.7 billion**

CHART A: Categorization of costs to treat diabetes in 2012

In the United States, the majority of the cost (107.4 billion dollars) associated with the treatment of this chronic disorder, diabetes, is associated with inpatient hospitalizations and the medications used to treat diabetes-related conditions (American Diabetes Association, 2013). Lundqvist et. al. (2016 p.29) contends that any medication or intervention implemented to decrease the risk of an inpatient hospitalization related to diabetes, or at least decrease the need for medications used to treat complications associated with diabetes, will likely be beneficial from a cost and health standpoint. As a pharmaceutical sales consultant, I presently market a medication classified as a GLP1 which has been proven to reduce the risk of several conditions that require hospitalizations (Hodgson and Kizior, 2014).

As the chart in Chart A indicates, the annual cost of medications used to treat diabetes in 2012 was 21.1 billion dollars (American Diabetes Association, 2013). A

more useful way to examine the cost of medications used to treat diabetes for this doctoral thesis is to review the monthly, annual, direct and indirect costs of these medications. This doctoral thesis will only examine the cost of FDA approved medications used to treat type II diabetes in the United States. The direct cost of diabetes medications is defined as the amount paid for a monthly or annual supply of medications used to treat type II diabetes in the United States (Lee et al., 2008). The average price of these diabetic medications in Georgia is based on price data from GoodRx.com. Most often, when the cost of medication is considered, there is an over emphasis on the direct monthly or annual cost of a medication rather than the evaluation of the cost of a medication in the context of the total cost to treat a patient with type II diabetes (Lee et al., 2008). Indirect cost associated with specific diabetic medications is defined as the cost to treat complications from specific diabetic medications such as hypoglycemia (low blood sugar), weight gain, fungal infections, increased risk of amputation or fractures (American Diabetes Association, 2017; Herman, 2011). In addition, hospitalization costs associated with complications related to type II diabetes contribute significantly to the indirect cost and hence total cost of type II diabetes treatment (Lundqvist et al., 2016). As previously noted, 107.4 billion dollars were spent in 2012 on medications used to treat diabetes-related complications as well as hospitalizations related to the disorder (American Diabetes Association, 2013). Needless to say, the non-medication related cost to treat diabetes is quite significant (American Diabetes Association, 2013; Lundqvist et al, 2016).

As a pharmaceutical sales consultant with NovoNordisk Inc., my primary goal is to effectively market my assigned product, Liraglutide, a medication categorized as a GLP1 used to treat type II diabetes. This medication has a high direct monthly cost to the diabetic consumer (Skidmore-Roth, 2015). However, the indirect cost of the medication in my portfolio is quite small to nonexistent when compared to the costs associated with the adverse events linked to other classes of medications approved to treat type II diabetes such as weight gain, cardiovascular risks and hypoglycemic episodes (American Diabetes Association, 2013). These adverse events are not routinely associated with Liraglutide, the medication in which I market for NovoNordisk, Inc. (Zhuo, Zhang and Hoerger, 2013). Needless to say, emergency department visits or hospitalizations related to GLP1 pharmacotherapy are indeed rare (Lundqvist et al., 2016; Robinson et al., 2013). In fact, Liraglutide, a glucagon-like peptide (GLP1), has been proven to decrease the risk of two expensive complications directly related to type II diabetes i.e. nonfatal myocardial infarction (heart attack) and stroke (Lundqvist, 2016; Marso et. al., 2016). Even though studies regarding GLP1 medications have proven to reduce the risk of complications and hospitalizations associated with diabetes, marketing medications with a high monthly direct cost is an added sales challenge (Marso et al., 2016; Du et al., 2014; Carnethon et al., 2010). Therefore, it is of utmost importance that indirect medication costs are considered when prescribing medications to treat chronic illnesses such as type II diabetes. This is important because my customers i.e. physicians, nurse practitioners, and physician assistants, are often forced to select medications from a drug formulary

with a low direct cost, meaning inexpensive or cheap medications due to managed care constraints (Nathan et al., 2006; Lundqvist et al., 2016).

2.2.5 Drug formulary and classes of medications used to treat type II diabetes

A medication formulary or drug formulary is a list of medications that are used to treat specific diseases and are the preferred treatment medications for a disease by health plans in the United States (Bradbury-Huang, 2010). In the United States, medications on a health plan's drug formulary are most often less costly to patients than medications that are not on the formulary (Friedhoff, 2009). According to Friedhoff (2009), health plans select medications to add to their medication formulary mainly based upon the actual pecuniary cost of the drug. Therefore, not all medications available to treat a specific disease are included in a health plan's medication formulary. For example, although there are three medications from the glucagon-like peptide (GLP1) agonist class used to treat type II diabetes on a daily basis, most health plans select only one GLP1 agonist to add to their medication formulary.

According to Hodgson and Kizior (2014), medications on a drug formulary are assigned to various categories known as tiers and these tiers range from tier 1 – tier 5 or tier 6. The tier level placement of a medication on a drug formulary in the United States is influenced by the actual monetary cost of a medication to the health plan (Menzin et al., 2001). Medications on tier 1 level are much less expensive than medications in the upper tier levels. Below is an example of the tiered system for a

drug formulary (https://www.planprescriber.com/medicare-part-d/drug-formulary/): Accessed: November 15, 2016

Tier 1 — Preferred generic drugs, lowest cost-sharing

Tier 2 — Non-preferred generic drugs

Tier 3 — Preferred brand-name drugs

Tier 4 — Non-preferred brand-name drugs

Tier 5 — Specialty drugs, highest cost-sharing

The tier level placement of a medication on a formulary determines the amount of out of pocket expense known as cost sharing. A patient has to purchase medication each month in order to continue pharmacological treatment. Balkrishnan et al., (2003) contend tier level placement of a medication significantly influence whether or not a patient will adhere to the prescribed medication regimen. This is primarily due to the out of pocket cost of the medication. Needless to say, when a medication has a high out of pocket cost, patients are much less likely to fill prescriptions and adhere to the medication regimen as prescribed (Fendrick and Chernew, 2006). When a patient purchases a medication and administers the medication as prescribed, this is known as adherence to medication therapy (Balkrishnan et al., 2003). According to Balkrishnan et al. (2003) and Lundqvist et. al, (2016) adherence to medication therapy has a significant impact on the total cost of care for a health plan. The implication concerning the total cost of care is one of several reasons health plans should emphasize additional criteria beyond direct medication cost when engaging in

the decision-making process of creating the medication formulary ~ including the categorization process of the medication tier levels.

In the United States, it is customary on the drug formulary Tier System for the brand named medications to be tiered at tier 3 or tier 4. As a result of this tiered categorization, brand name medications will generally have a higher out of pocket cost to patients than preferred generic drugs or non-preferred generic drugs (Balkrishnan et al., 2003).

Below is a modified table example of how the Tier System determines the patients' out of pocket cost for medications from a health plan in the United States, Blue Cross Blue Shield Medicare (*http://www.bcbsm.com/medicare/help/understanding-plans/pharmacy-prescription-drugs/tiers.html)* : Accessed November 14, 2016

Drug Tier	Drug tier meaning	Out of pocket patient cost
Tier 1	**Preferred generic drugs**	$1 to $3 for drugs in this tier
Tier 2	**Non-preferred generic drugs**	$7 to $11 for drugs in this tier
Tier 3	**Preferred brand name drugs**	$38 to $42 for drugs in this tier
Tier 4	**Non-preferred brand name drugs**	45% to 50% of the drug cost in this tier
Tier 5	**Specialty drugs**	25% to 33% of the retail cost for drugs in this tier

Chart B- Drug Formulary Tier System

http://www.bcbsm.com/medicare/help/understanding-plans/pharmacy-prescription-drugs/tiers.html. Accessed November 14, 2016

As mentioned earlier, based upon the drug formulary Tier System, the out of pocket cost to patients for preferred brand named drugs may cost as much as 3 to 5 times more than non-preferred generic drugs and considerably more than preferred generic drugs (Balkrishnan et al., 2003).

As Chart B indicates, non-preferred brand named drugs and specialty drugs which have the highest out of pocket cost to patients. Medications categorized as a GLP1, which I market, are likely to be assigned to either tier level 3 or 4. They are usually assigned to tier level 3 or 4 because these products are considered brand named products as discussed below.

2.2.6 Class of medications used to treat type II diabetes

According to the American Diabetes Association (2017, p.S66), there are 7 classes of medications most commonly used to treat type II diabetes in the United States and they are as follows:

Metformin

Sulfonylurea

Thiazolidinedione (TZD)

DPP – 4 Inhibitors

SGLT2 Inhibitors

GLP1 Agonist

Basal Insulin.

Chart C identifies these pharmaceutical agents along with important characteristics of each agent within the classes.

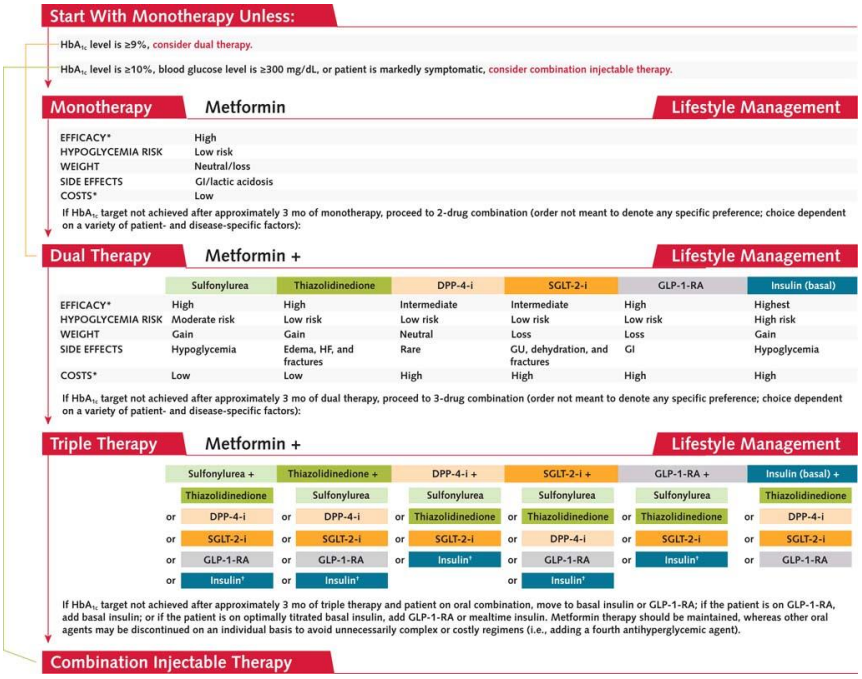

Chart C: American Diabetes Association (2017, S66) ~Pharmacologic Approaches to Diabetes Treatment

The above algorithm indicates that Metformin is the initial medication used to treat patients diagnosed with type II diabetes. When a patient is treated with Metformin and their type II diabetes remains poorly controlled, one or two medications from the remaining six (6) classes of medications are added to Metformin based upon treatment guidelines from the national organization, the American Diabetes Association (American Diabetes Association, 2017).

Later in this Chapter 2, the treatment recommendation for type II diabetes is discussed. In the meantime, I shall examine the characteristics of drug classes that are used to treat type II diabetes. These products affect the drug placement into a specific tier level within the drug formulary tier system.

Below, Chart D (a modified version of Chart C) is used to highlight some important differences among the various classes of drugs used to treat type II diabetes. The differences among the medications within and among the classes of medications used to treat type II diabetes will have an important impact on the direct and indirect cost of care. As a result, this will significantly influence the total cost of care delivered to the person diagnosed with type II diabetes. The identification of these differences plays an intricate role in the creation of this data-driven study. This data will aid in the creation of the discovery of the true comparison of health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. This discovery will, in turn, allow this writer to create an action learning plan designed to reveal a value-based rationale as to why the medications in which I market for NovoNordisk Inc. should be included on drug formularies and patients should have a low out of pocket cost for the medication as well. Recognizing the importance of cost, many healthcare providers as well as consumers are accessing the internet to compare prices. Thomas (2016) identifies GoodRx.Inc as one of the most popular internet – based research methods to compare the cost of medications. GoodRx, Inc. is a private company and is not affiliated with any company and the pricing is considered fair an unbiased (Thomas, 2016).

Metformin[A] – Recommended initial medication						
	Sulfonylurea	**TZD[1]**	**DPP[2]- 4 Inhibitor**	**SGLT2[3] Inhibitor**	**GLP1[4] Agonist**	**Basal Insulin**
Efficacy	High	high	intermediate	intermediate	high	High
Med Cost	Low	low	High	High	high	High
Hypoglycemia risk	moderate risk	low risk	low risk	low risk	low risk	high risk
Weight	Gain	gain	Neutral	Loss	loss	Gain
Side effects	hypoglycemia	edema, HF, fractures	possible heart failure	dehydration, GU, fractures	nausea	hypoglycemia

Chart D: Characteristics of Medications used to treat Type II Diabetes
(Modified version of Chart C)

As mentioned earlier, the cost of medication is a very important factor when health plans determine which tier level to assign medications on within a drug formulary. Review of Chart D reveals four (4) classes of medications used to treat type II diabetes that are considered expensive or "high" in cost:

DPP – 4 Medication Class

SGLT2 Medication Class

GLP1 Agonist Medication Class

Basal Insulin Medication Class

In addition to being "high" in cost, the medications in these four classes are considered brand-named medications. So, based upon the Drug Formulary Tier

System, the medications in these four classes will be assigned to either the tier level 3 or tier level 4 on a medication formulary. Villagra and Ahmed (2004) reveal that there are consequences when a medication is categorized at a tier level 3 or tier level 4. These consequences are related to cost. These cost related consequences are as follow:

a. Patients will have a high out of pocket cost for the medication
b. Due to the high out of pocket medication cost, patients may not purchase the medication
c. When patients do not purchase the medication, their risk for complications related to diabetes increase as well as their risk of being hospitalized
d. When patients do not purchase the medication due to the high out of pocket cost, the cost to a health plan is likely to increase due to the increased risk of hospitalizations and disease-related complications

It is important to note that in Chart D some classes of medication used to treat type II diabetes are associated with weight gain, hypoglycemia (low blood sugar), fractures, and heart failure. These are identified as indirect costs associated with medication. When these medications are prescribed, the potential adverse events should be considered. They should certainly be considered when attempting to make a determination of the true financial and overall cost of a medication ~ especially as it pertains to the patient's overall health (American Diabetes Association, 2017; Boyle et al.,2010). An extensive discussion of the medications used to treat diabetes is presented within the heading of *Overview of medications used to treat type II diabetes* later within this Literature Review.

Throughout the nineteen (19) years that I have been employed with NovoNordisk, I have marketed not only the medication categorized as a glucagon-like peptide but I have also marketed basal insulin as well. Respectively, these pharmaceutical agents are identified in the GLP1 agonist class and the basal analog insulin class. Both of these medications have been approved to treat type II diabetes (Inzucchi et al.,2012; Friedhoff, 2009) . As a pharmaceutical sales consultant, I have marketed these medications to healthcare professionals such as physicians, nurse practitioners and physician assistants throughout the state of Georgia.

Both of these medications are considered branded products, not generics. Based upon the Drug Formulary Tier System, these medications will generally be placed on the Tier 3 or Tier 4 level because they are categorized as branded products. As explained earlier, since these medications are on a higher tier level, the direct monthly medication cost to patients and health plans will be more expensive than medications on the lower tiered levels.

A cost comparison of different classes of medications used to treat type II diabetes in the United States is depicted in Chart E.

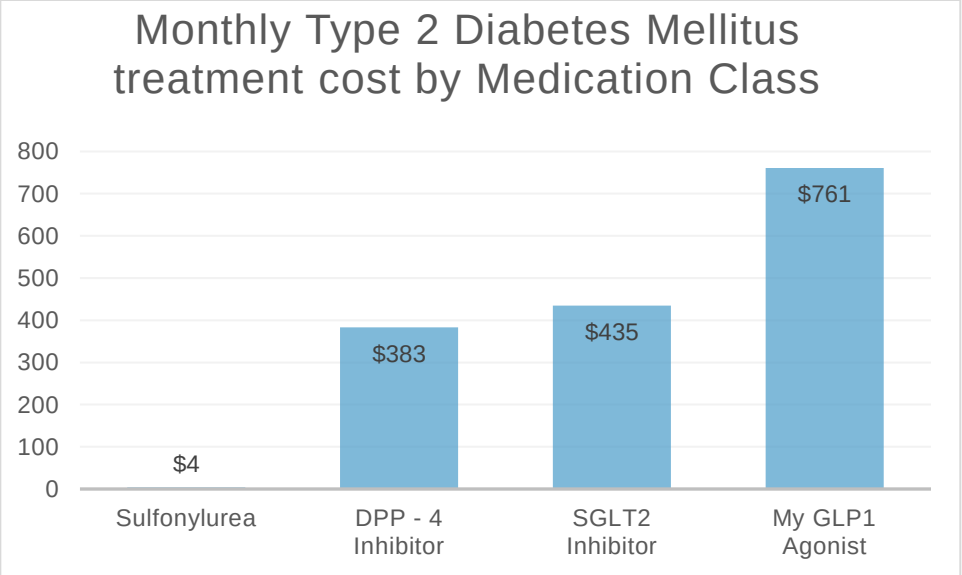

Chart E - Monthly Cost Type II Diabetes Meds by Class, GoodRx.com, 10/2017

The direct monthly cost of the GLP1 agonist medication, Liraglutide, is more expensive than the medications from the other classes used to treat type II diabetes. There are three classes of medications used to treat type II diabetes in the United States that have a safer side effect profile than the older generation of products used to treat diabetes (Nauck, 2016; McGuire et al., 2016) . These classes of medication are listed as follows: DPP4 (dipeptidyl peptidase 4) inhibitor, SGLT2 (sodium/glucose co- transport 2 inhibitor) and GLP1 (glucagon-like peptide) agonist. As identified in Chart E, among the three categories of medications used to treat type II diabetes in the United States, the GLP1 agonist, which I market (Liraglutide), is the most expensive medication within these three categories, depicted in Chart E .

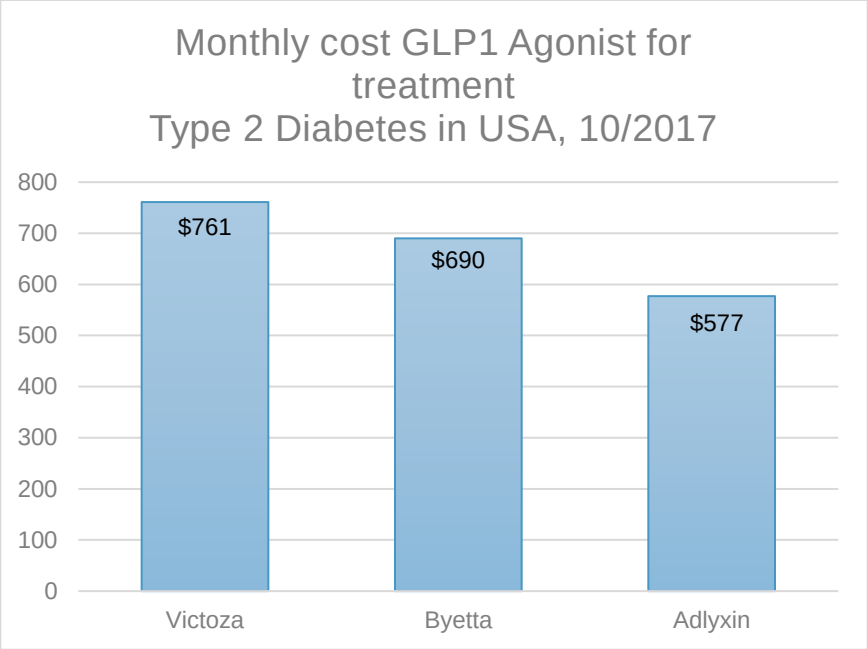

Chart F - Monthly cost GLP1 Agonist, GoodRx.com, 10/2017

A treatment regimen, which I have marketed in the past for NovoNordisk, Inc. known as basal analog insulin, is indicated to treat type II diabetes as well (American Diabetes Association, 2017). Basal analog insulin, sold by the vial and not by individual units, can be prescribed as a solo regimen or part of a combination treatment regimen (Rosenblum and Kane, 2003). According to the Standards of Care identified by the American Diabetes Association (American Diabetes Association, 2017; American Diabetes, 2019), the use of basal analog insulin has a safer side effect profile than NPH (Neutral Protamine Hagedorn) insulin. NPH insulin is a considered a generic product and is less expensive than the basal analog insulin. Basal analog insulin is considered peakless and is identified as a safer product because of the decreased risk of adverse events such as weight gain and hypoglycemia, especially nocturnal hypoglycemia (American Diabetes Association, 2017).

Upon review of the basal analog insulins, the basal insulin product manufactured by my workplace, Levemir, is not the most expensive; however, it is also not the least expensive either. Chart G represents the monthly cost of three basal insulin products in the United States of America.

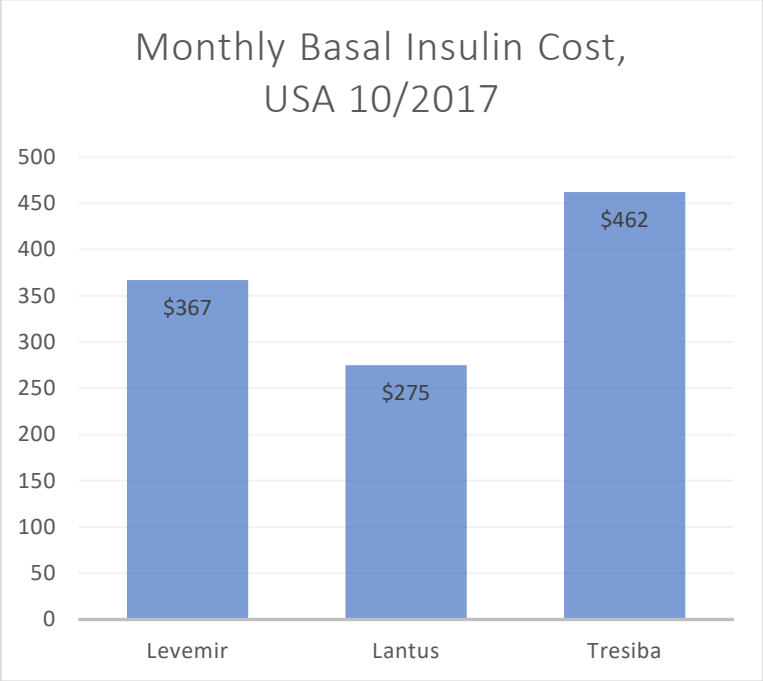

Chart G - Monthly Basal Insulin Cost, GoodRx.com, 10/2017

As represented in Charts E, F and G the monthly monetary cost of diabetes medicines in the United States may vary significantly. The two products in which I have marketed to treat type II diabetes are among the most expensive, in terms of the monthly monetary cost. As previously mentioned, the monetary cost of a medication is an important factor when determining if a medication will be placed on a drug formulary as well as which tier level a medication will be assigned (Balkrishnan et al., 2003).

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2.3 My Business Problem

The business problem I have as a pharmaceutical sales consultant is that the GLP1 agonist, which I presently market and the basal insulin, which I have marketed in the past, to treat type II diabetes are branded medications. The direct monthly monetary cost of these medications is traditionally more expensive than other medications used to treat type II diabetes (Skidmore – Roth, 2015). According to Hodgson and Kizior (2014), due to the higher direct cost of these medications, they are likely to be omitted from the drug formularies by health plans. Subsequently, when the medication(s) , which I market, are placed on drug formularies, patients will have a higher out of pocket cost. This higher out of pocket cost is due to the fact they are usually placed on tier level 3 or tier level 4 on the drug formulary plans. My business problem is even more challenging because physicians, nurse practitioners, and physician assistants are under pressure to keep cost down. As a result, these healthcare providers often avoid prescribing medications that are considered high "out of pocket" cost medications. It has been my professional experience that this remains true even when there is considerable clinical benefit to patients when higher cost medications are prescribed. Accessing evidenced based data to support this statement is challenging and one of the primary reasons for the development of this doctoral dissertation.

The breadth and depth of a sufficient literature review is interrelated. According to Altman and Anderson (2009), when attempting to embark upon relatively new territory within research the literature is often limited. In these cases, the viewpoints of the participants are often limited as well and the responses do not always reflect

the general population (Leedy and Ormrod, 2005). An insufficient sample size can potentially skew the results questioning the validity of the results (Easterby – Smith et al., 2008; Leedy and Ormrod, 2005).

2.3.1 My Action Learning Plan

It is not uncommon for patients or customers to purchase a more costly product when a less expensive product is available if the more expensive product can demonstrate a better value (Cheng et al., 2013). My Action Learning Plan demonstrates how products such as a GLP1 agonist and basal analog insulin are better value medications despite their higher monthly out of pocket cost. This is determined by properly analyzing the data. In order to properly analyze this clinical data, a Budget Impact Analysis and a Cost Effective Analysis seem most appropriate. According to Yagudina et al. (2017), the concept of combining a Budget Impact Analysis (BIA) and a Cost Effective Analysis (CEA) is common because it is evidence-based data that properly assesses the pharmaco-economic state of a chronic disease. Yagudina et al. (2017) explains that BIA is a structured examination of the financial impact of a new intervention, in my case, prescription medicines, on a system or a population. A BIA is usually performed from the perspective of a *Payer* or health insurance company. Applying an analytical tool, such as this, uses cost as well as the perspective of a *Payer*. This is beneficial to my business problem because the *Payers* are the entity that will ultimately determine which medications will be added to the drug formulary. It is important to note that the Payer or the health insurance company also determines the tier level on which the medication should be categorized. The BIA will be performed based upon criteria established by the

International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (Yagudina et al., 2017). A BIA is performed over a specific period, usually 1 – 5 years and involves specific scenarios. This type of analytical framework is helpful because the different scenarios I will examine are likely treatment regimens for type II diabetes in the United States versus revised treatment regimens for type II diabetes after a BIA and CEA. Importantly, I will examine out of pocket expense scenarios of patients and these scenarios will be heavily influenced by the cost of the medications.

Medication cost is one of the primary concerns within this concept. Edejer et al. (2003) defines a Cost Effective Analysis (CEA) as an analytical method to review the cost and health benefits of certain approaches to the treatment of a disease state. Usually, the overall disease state, present and previous treatment regimens are thoroughly evaluated.

Key parts of a BIA for my business problem are identified as follows:

1. Size of population eligible for treatment of type II diabetes
2. Likely treatment regimens based upon current drug formulary and Tier System
3. Cost of current treatment regimens and out of pocket patient expense
4. Revised treatment regimens after a BIA and CEA with revised drug formulary and Tier System
5. Cost of revised treatment regimens and out of pocket patient expense
6. Changes in type II diabetes related cost including complication development, cost or hospitalization or cost related to a revised treatment regimen

2012 Direct Diabetes Medical Expenditures, United States of America	
Diabetes Medications and Supplies	**$21.1 Billion**
Diabetes Hospitalization Cost	$75.7 Billion
Prescription Meds to Treat Diabetes Complications	$31.7 Billion

Skilled Nursing Facility	$14.1 Billion
Diabetes Physician Office Visits	$15.8 Billion
Other Diabetes Expenses	$17.6 Billion
2012 Total Direct Diabetes Medical Cost	**$176 Billion**

Chart H – American Diabetes Association, 2012: USA Direct Diabetes Medical Expenditures

Upon further review of this hypotheses emergence, it is crucial to reiterate the point that the lack of adherence to medication therapy will lead to an increase in the total cost to a health plan to treat a chronic disease, such as diabetes (Balkrishnan et al., 2003; Edejer et al., 2003). As you will learn as you read through this doctoral thesis lack of adherence to medication therapy for type II diabetes increases the risk of not only complications related to type II diabetes but hospitalizations as well (Bradbury-Huang,2010; Lundqvist et al., 2016). Needless to say, these are two reasons why health plans should have more expansive criteria beyond medication cost when determining the tier level placement of a medication on the drug formulary.

2.3.2 Direct Cost: Medications used to treat type II diabetes

In most cases, the predominant factor for determining the selection and categorization of a particular medication to a managed care formulary is a direct cost to the health care plan (Balkrishnan et al., 2003; Lundqvist et al., 2016). The decision-makers within the company simply want to know “how much will this medication cost the company”. Direct cost is also a primary concern of the consumer. According to

Lundqvist et al., (2016), the tier in which the medication is placed significantly impacts the patient's out of pocket expense for medications. Pricing / cost identified in the following direct cost charts aa through ee is indicated in **US dollars (USD).**

(Direct Cost Chart aa) Good Rx Fair Price cost difference for GLP 1Agonists: https://www.goodrx.com/glp-1-agonists (Accessed March 01, 2015)

GLP1 agonist Liraglutide	Competitor GLP1 agonist	Monthly cost difference	Yearly cost difference
761 per month cost	690 (Byetta)	71	852
761 per month cost	577 (Adlyxin)	184	2392
761 per month cost	730 (Trulicity)	(-)31	(-)372

(Direct Cost Chart bb) Good Rx Fair Price for GLP1 Agonist (Liraglutide) versus SGLT2 Inhibitors: https://www.goodrx.com/glp-1-agonists versus https://www.goodrx.com/sglt2-inhibitors (Accessed March 01, 2015)

GLP1 agonist Liraglutide	SGLT2 Inhibitor Cost	Monthly cost difference	Yearly cost difference
761 per month cost	453 Farxiga	308	3696
761 per month cost	450 Invokana	311	3732
761 per month cost	415 Jardiance	346	4152

(Direct Cost Chart cc) Good Rx Fair Price for GLP1 Agonist (Liraglutide) versus DPP4 Inhibitors: https://www.goodrx.com/glp-1-agonists versus https://www.goodrx.com/dpp4-inhibitors (Accessed March 01, 2015)

GLP1 agonist Liraglutide	DPP4 Inhibitor Cost	Monthly cost difference	Yearly cost difference
761 per month cost	420 Januvia	341	4092
761 per month cost	370 Onglyza	391	4692
761 per month cost	330 Tradjenta	431	5172

(Direct Cost Chart dd) Good Rx Fair Price for GLP1 Agonist (Liraglutide) versus Thiazolidinediones: https://www.goodrx.com/glp-1-agonists versus https://www.goodrx.com/thiazolidinediones (Accessed March 01, 2015)

GLP1 agonist Liraglutide	Thiazolidinediones	Monthly cost difference	Yearly cost difference
761 per month cost	12 Actos	749	8988
761 per month cost	174 Avandia	587	7044

(Direct Cost Chart ee) Good Rx Fair Price for GLP1 Agonist (Liraglutide) versus Sulfonylureas: https://www.goodrx.com/glp-1-agonists versus https://www.goodrx.com/sulfonylureas (Accessed March 02, 2015)

GLP1 agonist Liraglutide	Sulfonylureas	Monthly cost difference	Yearly cost difference
761 per month cost	7 Glucotrol	754	9048
761 per month cost	10 Amaryl	751	9012
761 per month cost	10 Glyburide	751	9012

An extensive discussion of the medications used to treat diabetes is presented within the heading of *Overview of medications used to treat type II diabetes* later within this Literature Review. The clinical components i.e, indications, benefits, adverse events and limitations of these categories of medications have been identified in its entirety.

When comparing the health benefits and cost savings of diabetes medications used to treat type II diabetes in Georgia, it is crucial to review the complications associated with diabetes. Addressing this workplace problem allows this writer to inform

healthcare providers and managed care administrators of the long term complications as well as difficulties encountered in managing the disease process of the type II diabetic patient. To clarify, according to the American Diabetes Association (American Diabetes Association, 2017), diabetes related complications can be identified as health conditions that affect those persons diagnosed with diabetes more often than the general population of non-diabetic persons.

The annual costs, in Georgia, associated to diabetes by managed care payer sources are dutifully noted in Chart I (American Diabetes Association, 2013). The managed care industry recognizes that the cost of treating the diabetic patient is a large contribution to the nation's debt (Lundqvist et al.,2016). These payer sources included Georgia Medicaid, private insurance and employer based insurance plans. Cost identified in the following charts is indicated in US dollars (USD).

GEORGIA
2013 Annual Costs Associated to Diabetes by Managed Care Payer Source

Payer source	Age Group	Millions (USD)	Cost per person (USD)
GA Medicaid	18-64	$268	$3439.10
	>65	$160	$2674.68
Private Insurance	18-64	$142.6	$5473.06
	>65	$249	$2183.02
Employer	18-64	$300.8	$9921.67
	>65	$210	$5781.07

CHART I

Treating a chronic disorder like type II diabetes can be troublesome for the aging population. The aging populations, those persons at the age of 65 and older, have diabetes and diabetes-related complications more often than the younger population of people in the United States of America (American Diabetes Association, 2017). It can be troublesome because it affects their ability to 'self-manage' their disease, especially if the cost of therapy is an issue (Edejer et al., 2003). Chart J is a chart that illustrates the Medicare data identifying diabetes-related diseases in Georgia in 2013. This is considered important because due to technology and advancements in medicine, people ages 65 and older are living longer and healthier lives (Center of Disease Control and Prevention, 2017).

GEORGIA
2013 Diabetes Related Diseases from Medicare Data

Diabetes Related Diseases	Total Number
Coronary Artery Disease	67,525.34
Chronic Kidney Disease	57,885.02
Peripheral Vascular Disease	31,987.59

CHART J

Chart K shows the hospitalizations in Georgia for the diabetes - associated conditions in 2014.

2014 Georgia Hospitalizations with Diabetes Associated Conditions

Medical Condition	Total Hospitalizations	Diabetes-Related
Heart Failure	13507	5760
Stroke	8230	
Myocardial Infarction	6333	1360
Lower Extremity Amputations (LEA)	3582	2900
***Hypoglycemia**	1882	1822
***Hyperglycemic hyperosmolar non-ketonic syndrome (HHNS)**	1113	1113
***Diabetic Ketoacidosis**	6937	6937

*Condition uniquely associated with blood sugar abnormalities

CHART K

Diabetes management in the United States is an expensive task shared by many such as the healthcare provider, managed care administrator as well as the consumer. According the American Diabetes Association (American Diabetes Association, 2017). On average the cost to treat an American diabetic person can cost up to ten thousand dollars more annually than to treat a person without this chronic disorder. The aforementioned data in Chart K illustrates the various costs associated with diabetes. Creating a plan of action to decrease the diabetes related complications would ultimately reduce the overall cost to treat the disease (Edejer et al., 2003). This plan of action includes a foundation of a cost effectiveness value-based model for formulary usage. The algorithm and value-based contract developed template is disease and value based. The theoretical framework of Herbert Simon, *Bounded Rationality*, supports the concept surrounding creating algorithms in order to support uniformity. According to Simon, it is through heuristic exploration that we uncover

new dimensions (Kalantari, 2010). As managers within the organization implementing a plan of action with the information that is readily available can be rewarding (Simon, 1990). The creation of algorithms can be quite beneficial as they create a "step by step" process to an identified problem, it is noted by management as a viable solution with quantifiable interventions and it is easily comprehended (Kalantari, 2010) . Upon review of the data, the following is noted to be depicted within the template:

a) Disease or condition, patient population, natural history, clinical course and outcomes.

b) Primary treatment options and the treatment process for each option – preferably based on treatment guidelines or actual practice

c) Costs of product and other medical resources consumed within each clinical pathway.

d) Outcomes of therapy for each clinical pathway

e) Incremental cost and outcomes analysis presented in cost/consequences tables and as cost-effectiveness ratios.

According to the Standards of Care created by the American Diabetes Association (2017), there is an algorithm for treatment for the person who has been diagnosed with diabetes. Clinicians in the United States routinely refer to these Standards of Care created by the national organization, American Diabetes Association when creating a plan of care for the person with type II diabetes (American Diabetes Association, 2017). The algorithm, as noted in Chart C, has been identified by the

American Diabetes Association for treating the person diagnosed with type II diabetes is as follows (American Diabetes Association, 2017):

In clinical pathway A, when the clinician diagnoses the person with type II diabetes, counseling is implemented to incorporate lifestyle changes including diet and physical activity. The standard of care guidelines recommended this counseling to be conducted via diabetes self-management training. In clinical pathway B, if the hemoglobin A1C is 9-10%, Metformin is recommended in combination with a sulfonylurea or GLP1 agonist. In clinical pathway C, if the hemoglobin A1C is greater than 10% then basal analog insulin therapy is recommended. The insulin is titrated until an acceptable range of an A1C of less than seven (7) is obtained. The hemoglobin A1C is reassessed after three (3) months of therapy. In clinical pathway D, if the hemoglobin A1C is seven percent (7) but less than eight (8) percent, a sulfonylurea, GLP1 agonist, Pioglitazone or a DPP4 inhibitor is incorporated into the regimen. In clinical pathway E, if the hemoglobin A1C is eight (8) percent but less than 8.5%, then a sulfonylurea, Pioglitazone or a GLP1 agonist is the therapy of choice. In clinical pathway F, if the hemoglobin A1C is greater than 8.5% but less than nine percent (9), a sulfonylurea or a GLP1 agonist is the therapy of choice. In clinical pathway G, if the hemoglobin A1C is greater than nine (9), basal analog insulin is the medication of choice. If the hemoglobin A1C is not less than seven (7) percent after three months, then the clinician shall continue with the aforementioned algorithm.

The aforementioned overview of the pharmacological agents used to treat diabetes, complications associated with diabetes, usage of budget impact and cost

analysis, as well as the algorithm associated with the treatment of type II diabetes creates tremendous insight into the emergence of the hypotheses for this doctoral thesis. As indicated in the overview, creating a budget impact analysis and a cost effectiveness analysis on the pharmacological agents used to treat type II diabetes provides true insight of the potential cost implications of these medications used to treat an entire cohort of Georgians who have been diagnosed with type II diabetes. In fact, the significance of a budget impact analysis and a cost effective analysis will be especially impactful when examining the comparison of health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia.

These study results will be even more impactful on my role as a pharmaceutical sales consultant who markets medication used to treat type II diabetes. The medication in my portfolio used to treat type II diabetes is associated with weight loss or at least, no weight gain. The budget impact analysis of the medication in which I market seems quite favorable when cost is viewed through a broader lens. A completed budget impact analysis and a cost effective analysis will be able to demonstrate to health plan decision makers the economic value of the medication in which I market. Demonstrating the economic and clinical value of a medication to health plan decision- makers is important because these decision makers determine which tier a medication is placed within in the medication formulary system. When marketing a medication with high "out of pocket" cost, this literary document will reveal that it is important to review the *true* cost of that pharmaceutical agent. This action-learning plan has been created to identify a framework that examines the *true* cost of medications used to treat type II diabetes. The *true* cost of a pharmaceutical

agent is viewed by assessing the overall value of the agent. This includes not only the direct but indirect cost of the agent as well.

2.3.3 Pathophysiology embedded within the conceptual framework

According to Powers (2005), diabetes mellitus (DM) is not considered a single disease; in fact, it is classified as a group of chronic diseases. Diabetes mellitus is often responsible for abnormalities in high blood sugars (hyperglycemia) and other metabolic complications due to a decline in the effectiveness of incretin hormones, an insufficient response to insulin and an excess of its opposing hormone, glucagon. The causative factor of hyperglycemia varies with the specific type of diabetes. All forms of diabetes create progressive metabolic changes that are damaging to the internal organs of the human body. Diabetes is actually classified as type I or type II. The classification is based on the etiology of the underlying development of the disease (ADA, 2013). According to Powers (2005), type I diabetes can be defined as an autoimmune disorder that leads to beta-cell destruction. This type of diabetes usually leads to absolute insulin deficiency and is responsible for about 5-10% of all diabetic cases (ADA, 2013). Type II diabetes is considered a progressive disorder caused by insulin deficiency and or insulin resistance. This form of diabetes accounts for over 90% of the cases of diabetes in America (ADA, 2013). Gestational diabetes mellitus is diagnosed during pregnancy (Powers, 2005). It is important to note that not all patients with diabetes can be identified within one category (ADA, 2013) (Harris, 2004). According to Harris (2004), an individual may appear to exhibit symptoms of type II diabetes but actually have a modified form of type I diabetes – in

this case the individual has what is known as type 1.5 diabetes. This disorder can also be identified as latent autoimmune diabetes in adults (LADA). There are often other, more rare, identified types of diabetes as well such as genetic defects of the beta cell functioning; genetic defects in insulin action; diseases of the exocrine pancreas, endocrinopathies, drug or chemical induced; or immune-mediated diabetes (Harris, 2004).

As mentioned earlier, type II diabetes is the most prevalent form of diabetes in the United States. An individual is diagnosed when he/she has low incretin levels, diminished pancreatic beta cell functioning (insulin deficiency), and/or an inadequate tissue response to insulin (insulin resistance) (Harris, 2004). The hepatic system usually produces an excess amount of glucose and the cells within the muscles do not absorb an ample amount of glucose (Harris, 2004). Even though genetics may play a role in the progression of this disease, obesity is the leading factor in type II diabetes (ADA, 2013; King et al., 1998; Harris, 2004).

Farooqi (2011) defines obesity as a disease encompassing a number of influential factors. These factors associated with obesity may include one's standard of living, socio-economic status, familial history, psychological and or physiological components. According to Mokdad et al (2001) and the Center of Disease Control (2014), there is a gender difference in the prevalence of obesity. Amongst men the prevalence of obesity is generally similar at all income levels as well as education. In women, however, the prevalence of obesity increases with the female who is less educated with lower income levels. In the United States, obesity seems to affect certain cultures more so than others (Center of Disease Control, 2014). According to

the Center of Disease Control (2014), the rates of obesity are as follow: 47.8% in non-Hispanic blacks, 42.5% in Hispanics, 32.6% in non-Hispanic whites and 10.8% in non-Hispanic Asians. Ogden et al. (2012) reveals that obesity is not always related to genetics and is often affected by environmental factors within a culture because of the impact it has on the eating habits of an individual. Families have a tendency to share the lifestyle habits of their family and friends (Center of Disease Control, 2014). Individuals are more likely to be obese if they have family and friends who are obese. Ogden et al. (2012) contends that obesity is often a disease that is stigmatized by society. It is important to recognize that the attitudes of personnel, researchers and even other study participants must be considered during the interview process regardless of the study topic (Keegan, 2009; Leedy and Ormrod, 2005). Berthoud (2012) contends that in the past fifty years the lifestyle changes within the United States have contributed to the increase incidences of obesity. The changes include the increase foods with higher fat content, busy lifestyles with less rest and a lack of energy expenditure. According to Davis (2013), there is a biological predisposition to consume more calories when high calorie foods are readily available. This has been referred to as being in an obesogenic society – one that promotes the acquisition of obesity. Throughout the world our professions have changed and the physical activity has been altered in the work environment as a result (Davis, 2013). In fact, there are very few jobs in the United States that are associated with strenuous physical movement and Americans are not usually compensated by voluntarily increasing their physical activity (Herring et al., 2014). As a society, Americans are not known for great physical activity. In fact, according to Davis

(2013), many Americans spend quite a bit of time watching television or in front of the computer. In addition, Americans primarily rely on their cars for transportation. Schmidt et. al, (2014) report the contributions of the metabolic burden of sleep loss as it relates to the increased body weight and obesity. The study reveals that the number of hours of sleep correlated negatively with the body mass index (BMI); the less sleep individuals had, the higher the BMI. Furthermore, those persons who sleep less than five hours per night had an increased risk of obesity. Lack of sleep can result in hormonal changes within the body resulting in an increase in appetite – particularly for foods that are high in calories (Schmidt et al., 2014).

According to Ul-Haq et. al (2013), obesity is identified via classifications. An individual with a BMI (Body Mass Index) of 25.0 - 29.9 is considered overweight. The classifications of obesity are as follow: Class I is considered a BMI of 30 – 34.9; Class II is considered a BMI of 35 – 39.9; Class III is considered a BMI of greater than 40. According to Caro et al. (2002), type II diabetes, is a weight related comorbidity associated with diabetes and satiety is a major factor when considering treatment.

The pathophysiology of satiety is an important aspect of obesity and is linked to GLP-1. As mentioned earlier, the medication in which I market is classified as a GLP-1 receptor agonist. Satiety can be explained via a further understanding of molecular mechanisms. Simpson et al. (2008) reports that ghrelin activates the signal of ‘hunger’. A person with normal body functions has levels of ghrelin that increase during fasting periods and decrease in response to an intake of glucose. The pathophysiology of satiety can be further explained by providing a more

comprehensive review of satiety signals. Suzuki et al (2012) reveal that satiety signals can be separated into a couple of categories. The first category can be identified as short-term signals. Short-term signals are noted in the immediate responses to an intake of food and include a number of signaling molecules originating in the intestinal tract. One of these key signals is glucagon-like peptide (GLP-1). The long-term signals, on the other hand, include insulin and leptin. These are different and are known as adiposity signals because their production is linked to the amount of adipose tissue, also known as fatty tissue, in the human body. Natural GLP-1 is secreted from L-cells of the intestine following ingestion of food in proportion to the amount of calories ingested and its levels decrease during fasting states. GLP-1 has a number of physiological functions as well (Vrang et al., 2010). For instance, GLP-1 regulates glycemic control by both stimulating insulin secretion and decreasing glucagon secretion in a glucose-dependent manner. Additionally, GLP-1 contributes to energy homeostasis by reducing appetite and energy intake. Furthermore, it also decreases gastric acid and gastric emptying.

The long-term signals of satiety include hormones known as leptin and insulin. Leptin is involved in the long-term regulation of energy balance and appetite. Schwartz et al.,(2000) reveals that it is actually a satiety signal that is synthesized and secreted directly by fat cells at levels of proportional to adipose tissue mass in the body. Leptin plays a role in immune functions, hematopoiesis, angiogenesis and bone development. Leptin is also responsible for regulating glucose metabolism independently of energy balance (Kershaw et al., 2004). This decreases ones appetite and body weight and increases energy expenditure. Kershaw and Flier (2004)

contend that in animal models, leptin actually stimulates gluconeogenesis and inhibits glycogenolysis while improving insulin resistance. Leptin also induces thermogenesis through the sympathetic nervous system by increasing spontaneous physical activity and reducing metabolic efficiency. A decrease in leptin levels, as a result of reduced food intake and weight loss, causes an adaptive physiological response, characterized by increased appetite and decreased energy expenditure (Kershaw & Flier, 2004). According to Kershaw and Flier (2004), obesity is a chronic disease. Persons who have been diagnosed with obesity usually have elevated levels of leptin in their bloodstream. However, these studies indicate that these individuals do not experience a decreased appetite and increased energy expenditure. This disorder is known as leptin resistance (Kershaw & Flier, 2004). The second long term signal associated with satiety is the hormone, insulin (Schwartz et al.,2000). As a pharmaceutical sales consultant for NovoNordisk, I market a long-acting insulin product called Levemir. Insulin is actually a life-saving hormone produced by the beta cells within the pancreas. As a human ingests food, insulin is synthesized and secreted in the body. An individual's insulin levels circulate in proportion to adipose tissue mass (Suzuki et al., 2012). Insulin is an important hormone that is responsible for decreasing blood glucose levels. In a healthy person, this normal body function happens as a homeostatic response to elevated blood sugars (Gerich, 1993). This communication of body signals promote the sensation of satiety and ultimately causes weight loss in the individual (Morton et al., 2011; Menzies et al.,2012). It is important to recognize that long-term release of insulin occurs if blood sugar levels remain elevated in the human body. These two chronic

disorders, obesity and type II diabetes, are both characterized by insulin resistance. According to Morton and Schwartz (2011), insulin resistance is a condition signified by elevated circulating insulin levels in the body.

2.3.4 Epidemiological cost factors

In this action learning based research, it is important to recognize the etiology and the disease course as well as the epidemiology of diabetes in order to understand the level of intensity created by this epidemic on the healthcare system in the United States. Powers (2005) contends that obesity is the culprit in the midst of this epidemic. In fact, it is the centrally obese individual that has issues with the fat accumulating around the intra-abdominal organs which often causes long- term complications associated with diabetes (Harris, 2004). As our culture evolves with age, the complications associated with chronic disorders such as diabetes have been responsible for creating a greater healthcare awareness within the nation (Dybicz et al. 2011). As a result of this heightened level of awareness, healthcare in the United States is undergoing significant reform and decreasing the rising cost of healthcare is a big part of this reform (Doherty, 2013). An important contributor to the rising healthcare cost seems to be the increased incidence of type II diabetes among obese patients and elderly patients. In fact, the ADA (2013) reports that the total cost of diabetes related care increased from 170 billion dollars per year in 2007 to 245 billion dollars per year in 2012, a staggering 41% increase in cost . Interestingly, 43% or 69 billion dollars per year is the amount spent on the care of diabetic patients in inpatient facilities such as hospitals, nursing homes or hospice care to treat chronic

complications of diabetes (ADA, 2013). Therefore, any intervention that minimizes chronic complications can lead to a substantial cost savings (ADA, 2013). According to the American Diabetes Association, 12% or 21.12 billion dollars is the amount spent on medications used to treat diabetes and diabetes supplies (ADA, 2013). What may surprise many is that 31.68 billion dollars per year is the amount spent on medications used to treat the complications associated with diabetes. Therefore, about 10 billion dollars more per year is the amount spent on medications used to treat the complications of diabetes alone than on medications used to treat the actual disease of diabetes itself.

Choo (2006) contends creating a knowing organization, which is fully explained in section 2.4 through 2.4.4, can be accomplished through extensive research of the literature. The literature reveals a number of studies addressing the correlation of knowledge level and cost/benefit analysis of those individuals suffering from chronic illnesses such as diabetes.

To begin with, the literature reveals that early intensive outpatient pharmacologic therapy or intensive lifestyle modifications are cost effective long term therapies in the treatment of diabetes because these approaches decrease the chronic complications associated with poorly controlled diabetes, especially cardiovascular and renal complications in the elderly (Saydah et al., 2004; Carmethon et al., 2010). A strategy of reducing these complications will have a significant impact on not only the cost of in-patient care but also on the cost of medications used to treat the complications of diabetes (Loeppke et al., 2009 ; Brown et al., 1999; Boyle et al., 2010). Although all aspects of healthcare are being reformed limiting the cost of

prescription medications is a major part of lowering the cost of healthcare (Kahn and Anderson, 2009). In the industry of pharmaceutical sales , when a prescriber restricts a patient's access to brand name medications through the use of medication formularies and tiered co-pay pricing for prescription medications also (theoretically) decreases the cost of healthcare. In the United States, a tiered co-pay pricing system provides generic medications at a discounted price. It is considered a "cheaper price" as compared to brand name medications. For instance, the "out of pocket cost for the patient" of a generic medication has a discounted price of 4 US dollars for a 30-day supply of medication versus 35US dollars or 75US dollars for a 30-day supply of a brand name medication in the same class. It is important to emphasize that the discounted priced generic medication is usually within the same medication class; however, the medications are not the bio-equivalent. For example, Skidmore-Roth (2015) reveals that insulin is considered a class of medication and within the class of medications that are categorized as insulin, there are several brand name insulin products identified in the categories as human insulin and analogue insulin. The tiered copay pricing system for medications and the medication formulary system consider all medications within the class of insulin products to be bio-equivalent. Insulin selection within the tiered copay system / medication formulary system is heavily influenced by the cost of insulin. The older (human insulin) brands are usually chosen as a treatment option by the healthcare provider because they are cheaper; however, they are less sophisticated and are associated with more adverse events than the newer (analogue) insulins (Skidmore-Roth, 2015). As a stakeholder within the pharmaceutical industry in favor of brand named medications used to treat

type II diabetes, this cost difference between generic medications and brand name medications is a primary concern. Our company hires a sales force to market the insulin analogue products. Restricting the access to brand name medications, due to medication formularies, imposes a tremendous strain on the sales volume of brand name medications. The idea of all medications within a specific class being labelled as bio-equivalent is simply incorrect. For example, under the bio-equivalency idea, genetically engineered insulin products are considered to be bioequivalent to regular insulin and this is simply not true (Jameson, 2006 p. 319). This bio-equivalence explanation is advanced simply so medication selections for the tiered system and medication formulary system can be heavily influenced by the cost of medications. Although most generic medications and older brand name insulin products, especially a class of medications known as sulfonylureas, insulins, are effective in controlling diabetes, the adverse effects are significant in terms of treatment (Jameson, 2006 p. 321). These adverse effects include weight gain and hypoglycemia. The weight gain component is inter- linked to cardiovascular disease, obesity, kidney disease, and various other risk factors (Mokdad et al., 2001). When the healthcare and human cost associated with the adverse effects of these generic medicines or older brand name insulin products are calculated, then these medications are not as *cheap* as they may seem (Kim, 2007; Loeppke et al., 2009).

Secondly, the UKPDS (1998) study is considered the gold standard as it relates to treating diabetes. One of the reasons for being considered a "gold standard" study is associated with the fact that the study is considered reliable and valid. Establishing reliability and validity are pertinent factors because it allows the researcher to gain

well-founded and correct outcomes. It is also instrumental in generalizing the findings to an expanded population of people. According to Coghlan and Brannick (2010), being able to relate to a wider population enhances the ability to apply the research results to a wider range of people in an effort to improve the lives of others who are affected by the research topic(s) (Coghlan and Brannick, 2010; Leedy and Ormrod, 2005). The UKPDS (1998) study reveals the weight gain component of pharmacological therapy has been the center focus of the treating the chronic disease, diabetes, for quite some time. The literature reveals that the rate of the category of 'severely obese' in the United States is rising more rapidly than the population who has been defined as 'moderately obese' (Unick et al., 2011; Ogden et al.,2014). To further explain, the term 'severely obese' refers to the person who is 100 pounds or more above their ideal body weight or has a BMI greater than 40. Regardless of the teachings concerning healthy eating habits, exercise and the consequences associated with weight gain, the population of people at the 'moderately and severely obese' rate continues to rise at a steadier rate than any other category of obese people (Unick et al., 2011; Ogden et al., 2014). In fact, the 6.6% of the American population is considered severely obese. A decade ago, the rate was at 3.9%. If Americans should continue this pattern, statistics show that by the year of 2030, this percentage should be at a rate of 11% (Flagal et al., 2012). The rate of moderate obesity is increasing in America as well. In fact, in the year 2000, 31% of Americans were considered obese. By the year 2010, the rate had increased to 36% of the American (adult) population (Flagal et al., 2012) Statistics show that expected percentage is to be 42% by 2030 (Ogden et al., 2012). If this is accurate, the number of obese people in the United

States is growing at an accelerated rate – surpassing the actual growth of the population of the American people.

2.3.5 Overview of medications used to treat type II diabetes

The FDA approval process is often a rigorous one in the United States (Friedhoff, 2009). At the time of this investigative study, there were six classes of medications approved to treat type II diabetes. These six classes of antidiabetic agents are categorized into four areas based upon their mechanisms of action (MOA). These pharmaceutical agents target the various steps involved in blood glucose regulation including intestinal absorption of glucose, pancreatic insulin secretion, hepatic glucose production, glucose uptake by muscle and fat cells and glucagon-like peptide 1 (GLP-1) regulation.

Secretagogues are oral antidiabetic agents that function by stimulating the beta cells in the pancreas to secrete more insulin. They are only effective with the individual who has a pancreas with functioning beta cells. Since type I diabetic individuals do not have functioning beta cells, the secretagogue is ineffective for the type I diabetic. They are ineffective primarily because these individuals require exogenous insulin because their pancreas is no longer able to secrete insulin from the beta cells (Dybicz et al.,2011). Sulfonylureas (SUs) have been available for over fifty years and are classified as either first-generation, second generation or third generation agents. According to McCann (2007), these second-generation SUs were approved by the FDA over thirty years ago. These secretagogues are available as

generic prescription drugs and are often the “treatment of choice” for type II diabetics in America due to cost.

Secretagogues are indicated as an adjunct to diet and exercise to decrease the blood glucose levels in patients with type II diabetes whose elevated blood glucose level is uncontrolled. SUs are also indicated for combination therapy along with the biguanide, Metformin. There is one SU, Amaryl (glimepiride) that is indicated for combination therapy with insulin. The ADA and AACE standards recommend SUs (along with other pharmaceutical options) as second line treatment for individuals with type II diabetes. Metformin is considered the ‘gold standard’ and is preferred as the first-line oral agent because of the low risk of adverse events when compared to the category of SUs (AACE, 2007) (Kooy et al., 2009). Individuals diagnosed with type II diabetes who are not overweight or obese may be appropriate candidates for SU therapy. The mechanism of action for the sulfonylurea is dependent upon the pancreatic beta cell function. According to McCann (2007), sulfonylureas operate by imitating the effects of circulating blood glucose on stimulating insulin secretion from pancreatic beta cells. The increased insulin concentration decreases blood glucose levels; however, it can also increase the chances of experiencing a decrease in the body’s blood sugar. This triggers a condition known as hypoglycemia. This is considered an adverse event because the SU-stimulated insulin secretion is implemented whether the individual has an elevated blood glucose level or not. In other words, the mechanism of action of the sulfonylurea is not glucose dependent and could result in a hypoglycemic episode (Krentz and Bailey, 2005).

The first, second and third – generation SUs vary as it relates to potency, safety, dosing and pharmacokinetics. The first-generation SUs include agents such as acetohexamide (Dymelor and generics), chlorpropamide (Diabinese and generics). Tolazamide (Tolinase and generics) and tolbutamide (Orinase and generics). According to Krentz and Bailey (2005), this class of medication is not considered as effective as the second-generation SUs. They are also not recommended as first line treatment for type II diabetes. Due to the lack of efficacy in these first generation SUs, higher doses are often required. With the higher doses, there are greater chances of experiencing adverse events such as hypoglycemia (McCann, 2007). Because the first generation SUs have a lower binding affinity to SURs in the pancreas and must be given in higher doses than second-generation agent they tend to bind securely to plasma proteins. This action may cause an interaction with other pharmaceutical agents that bind to plasma proteins. This can be dangerous because it intensifies the actions of the SUs or other medications being processed in the body (McCann, 2007). The medication Chlorpropamide, in fact, is the only first generation SU still in use today in the United States. The duration of action of sixty hours creates a concern for many healthcare practitioners because of the likelihood of hypoglycemia as compared the second-generation SUs (DeFronzo and Nauck, 1999). The second-generation SUs are fifty to two hundred times more potent than the first-generation agents. Consequently, the treatment regimen requires smaller doses. Most second-generation SUs have a decreased risk of hypoglycemia compared to the first-generation agents. Providers are more likely to prescribe second-generation agents because the potential to interact with other agents is greatly diminished

(DeFronzo, 1999; McCann, 2007). Glimepiride (Amaryl) is widely used in the United States and is a third-generation SU. Glimepiride has the lowest potential for hypoglycemia than any of the other SUs, has more modulated insulin release and the treatment regimen is once a day. All SUs are well absorbed and metabolized via the hepatic system. However, the elimination process of the medication varies among the unique compounds (Davis, 2004). The primary advantages with the SU category include efficacy and cost. Due to the fact that all SUs are generic, they are inexpensive compared to other antidiabetic agents on the market (Nathan et al., 2006). There are some limitations to the SU category. As mentioned earlier, hypoglycemia is a common adverse event and it occurs most often in the longer acting agents and the first-generation agents. These medications are eliminated through the kidneys, individuals must be cautioned that hypoglycemia becomes a greater potential for the person with a compromised renal system. Dosages need to be altered in this particular population of patient (DeFronzo and Nauck, 1999). Weight gain is another adverse event worthy of notation. According to Nathan et al., (2006) , individuals prescribed SUs gain an average of 4.4 pounds per year. Donath et al.(2005) reports that SUs may also result in pancreatic cell burnout. When an individual experiences pancreatic cell burnout, exogenous insulin is prescribed as treatment. The healthcare provider and other stakeholders within the industry must recognize that this may result in a limitation with regard to long-term durability in maintaining glucose control. SUs duration of action lasts up to 12-24 hours. Many of the first-generation sulfonylureas require two or three doses per day. Individuals who are required to take medications more than once a day often fail to comply

(DeFronzo, 1999). The second-generation agents are prescribed once or twice daily (Davis, 2004). They also carry an increased risk of cardiovascular mortality (Davis,2004). In the United States, cardiovascular studies are of utmost importance when approving medications used to treat diabetes. In fact, this original warning was due to the results of the University Group Diabetes Program (UGDP) in the 1970's (Knatterud, 2005). However, the findings of the United Kingdom Prospective Diabetes Study (UKPDS, 1998) contradicted these findings and did not agree with the results of this University Group Diabetes Program (UGDP).

The meglitinide class consists of two agents: repaglinide (Prandin) and nateglinide (Starlix). These agents were approved by the FDA in 1997 and 2000, respectively (Krentz & Bailey, 2005). These meglitinides are indicated to be used alone to treat type II diabetes or they can be used in combination with an agent such as Metformin or thiazolidinedione (TZD). Those patients whose blood sugars have a tendency to spike after meals or those who have a history of experiencing hypoglycemic episodes may benefit from this type of therapy (McCann, 2007). According to McCann (2007) blood sugars that are "too low" are known as hypoglycemic episodes and they can be dangerous.

The mechanism of action of Repaglinide stimulates rapid, short-lived pancreatic secretion of insulin. This mechanism of action allows the individual to "treat when he eats". Due to the fact it binds to a different site on pancreatic beta cells and for a shorter time than do SUs there are less chances of hypoglycemic episodes (Krentz and Bailey, 2005, p.395). Repaglinide is glucose-dependent which means it will assist the pancreas to release insulin only when there is a 'glucose load' noted in the

body – such as during mealtime. Therefore, Repaglinide is prescribed to be taken before meals. It generates a relatively short effect of about 180 minutes. This coincides with the amount of time it takes food to digest in the human body (Krentz and Bailey, 2005).

There are some advantages and limitations of Repaglinide therapy. A clear advantage is the fact that it is thoroughly absorbed from the gastrointestinal (GI) tract. This medication actually peaks in about 60 minutes after dosing and secreted primarily in the feces. This is an advantage because often times the person diagnosed with type II diabetes has a number of other medications on board affecting the renal system (Krentz and Bailey, 2005). Due to the fact that it is processed via the hepatic system, an increase in the half-life of the medication may occur if the liver function is poor. This may cause a hypoglycemic episode. Repaglinide is not recommended for those patients in diabetic ketoacidosis nor is it recommended for the patient who has been diagnosed with type I diabetes. Older patients, those who are suffering from undernourishment or malnutrition, hepatic or renal disease should be monitored for low blood sugars - especially if Repaglinide is being used to treat type II diabetes in this population.

Overall, the advantages of Repaglinide include its effectiveness, precipitous onset, and the limited amount of time that the medication is in the human body. With this limited time that the medication is in the body, the probability of hypoglycemia is greatly reduced. The A1C is expected to drop by 1.5 percentage points (Nathan, 2006). There are a few limitations to the product as well. The limitations include the multiple dosing times, weight gain and the out of pocket cost. The cost is usually

more expensive than the SU. The patient should "treat when he/she eats". The regimen is usually three to four times per day, depending on the meal schedule of the patient. The medication is taken zero to thirty minutes before the meal. Taking multiple doses of medication can often lead to non-compliance (Nathan, 2006).

Nateglinide (Starlix) is in the meglitinide category and is chemically unrelated to SUs. This medication has a mechanism of action to secrete insulin in a similar manner as the aforementioned Repaglinide (Nathan, 2006).

Like repaglinide, the action of nateglinide also begins quickly when food has been ingested. Again, one of the advantages of this type of medication is that it is glucose dependent and the duration of action in the human body is short-lived (Nathan, 2006). In fact, this is one of the major advantages of nateglinide - the rapid absorption. The peak plasma concentration of this product is about 60 minutes and it has a half-life of about 1.5 hours. A dose of nateglinide can be absorbed and stimulating insulin secretion from the pancreas within twenty minutes. This is a positive attribute, especially if the person is not sure when the food will be served. According to Nathan (2006), it is secreted primarily from the body in the urine; however, it is metabolized in the liver. It should be prescribed with caution in the patient who has been diagnosed with moderate to severe liver disease. It is not indicated to be used in patients with type I diabetes or those patients in a diabetic ketoacidosis state. The leading advantage of nateglinide is the shortened duration of action. The rate of hypoglycemic episodes is decreased when the duration of action of the medication is short. There are some limitations to the nateglinide therapy. The effectiveness, frequent dosing and cost are the limitations identified in the literature

(Nathan, 2006). Compared to other agents in the marketplace, the overall A1C reduction of one percentage point is considered subpar (Nathan, 2006). Compliance is an issue, as it has to be dosed several times during the day – with meals. The nominal cost is also more expensive than the SU's. The ADA consensus guidelines do not endorse their use of meglitinides and the AACE guidelines recommend these agents as alternatives to SUs only in select patient populations (Nathan, 2006; AACE, 2007).

In summary, the medications categorized as secretagogues stimulate the beta cells in the pancreas to create and secrete the life-saving hormone, insulin. The pharmaceutical agents in this category include SUs, meglitinides and amino acid derivatives. They all have mechanisms of actions that involve connecting to the SUR (sulfonylurea receptors) on the pancreatic beta cells.

The sensitizer is another category of medication used to treat the patient with type II diabetes. Unlike the aforementioned group of secretagogues, sensitizers do not increase insulin release from the pancreas - which may contribute to a condition known as "beta-cell burnout" (McCann, 2007). The medications identified in the sensitizer OAD (oral anti-diabetic) class act by heightening the sensitivity of insulin in the peripheral tissues within the body (i.e., muscle and fat). This class also improves insulin action in these tissues as well as process the glucose more efficiently at the cellular level. The medications in this class include metformin and thiazolidinediones (TZDs). TZDs work more on the peripheral tissues whereas metformin acts more on the hepatic system (McCann, 2007).

Metformin (Glucophage and Glucophage XR) is the only biguanide available for clinical use in the US. The FDA approved Glucophage in 1995 and Glucophage XR in 2000. As with all medication used to treat type II diabetes, metformin and extended-release metformin monotherapy are indicated to be used as an adjunct to low calorie meals and increased activity in an effort to improve blood sugars in persons who have been diagnosed with type II diabetes (Kooy et at., 2009). Metformin is indicated for patients 10 years old or older, and the extended-release metformin may be used in conjunction with a SU or insulin in patients 17 years old or older. The two agents may be prescribed with an SU or exogenous insulin in patients who are seventeen and older (McCann, 2007). Both forms of Metformin are available in generic forms in the pharmacies across the United States. In some pharmacies, this medication is free.

According to the ADA standards, metformin is the recommended first-line therapy for managing hyperglycemia in patients with type II diabetes, a position formerly held by SUs (Nathan, 2006). This change in position occurred due to metformin's effectiveness, low side effect profile, wide acceptance among the healthcare industry and the patients, and low cost (McCann, 2007). According to McCann (2007, p. 106), metformin is an ideal medication for the patient who has an elevated A1C, dyslipidemia, overweight or is insulin resistant.

Metformin is indicated for treating patients with type II diabetes either as monotherapy or in combination with a SU, TZD, meglitinide, exenatide, acarbose. or insulin.

Kooy et al (2009) reveal that the exact mechanism of action of a biguanide is unknown. However, it appears that metformin can affect blood glucose control in a couple ways. First, it diminishes the volume of glucose that the liver creates by lessening the amount of blood glucose produced from adipose tissue and protein and by inhibiting the breakdown of glycogen to glucose. Through this mechanism of action, metformin can improve fasting blood glucose levels. Metformin also, to some level, improves cellular glucose uptake and utilization; that is, it helps the body to use its own endogenous insulin appropriately. Unlike SUs, metformin does not have any impact on the amount of insulin secreted from the pancreas. Therefore, the chance of experiencing hypoglycemia with the use of a biguanide as monotherapy is diminished.

According to Nathan et al. (2006), there are advantages and limitations associated with the class of medication called biguanides. To begin with, metformin is a first line treatment of choice with patients diagnosed with type II diabetes (AACE, 2007). Due to the mechanism of action, it is noted to be a highly effective agent with low rates of hypoglycemia. The ADA and AACE consensus guidelines both support its first-line usage in addition to decreased calorie intake and increased activity in those patients, which are able to take this class of medication (Nathan et al. 2006; AACE, 2007 p. 262-263). The efficacy of this metformin as monotherapy is certainly remarkable. This agent is known to create a reduction of the A1C by 1.5 percentage points (Nathan et al., 2006). According to Nathan et al. (2006), there is some noted weight loss associated with the class as well; however, it may be partially due to the gastrointestinal side effect, such as diarrhea.

Even though, metformin and extended-release metformin usually do not cause hypoglycemic episodes directly, this adverse event may occur when it is combined with other agents such as a SU or insulin (Nathan et al., 2006). Studies also suggest reductions in microvascular complications associated with diabetes when metformin is used as treatment for the patient with type II diabetes (DeFronzo and Nauck, 1999 p. 293) (Kooy et al., 2009). Metformin also appears to have a favorable effect on serum lipids; some studies have found decreased LDL cholesterol and triglyceride levels, and slightly increased HDL cholesterol (Edwards et al., 2008). Extended-release metformin has convenient, once-daily dosing, usually with the evening meal. The maximum dose should not exceed 2000 mg in adult patients. Plain metformin, on the other hand, is ordered to be administered two to three times a day, which can be inconvenient and may interfere with compliance. Metformin, regardless if it is the extended release form or not, should be titrated slowly. The titration process is recommended in order to decrease any chances of gastrointestinal system adverse events (Kooy et al. 2009). The dosing schedule of immediate release (IR) metformin varies, depending on the patient. The usual regimen involves dosing the medication along with the meal. The maximum daily dose should not exceed 2550 mg in adults or 2000 mg in pediatric patients (Nathan et al., 2006).

There are some limitations associated with metformin dealing primarily with gastrointestinal adverse events. According to Nathan et al. (2006), the most common adverse events associated with metformin therapy include gastrointestinal events such as diarrhea and nausea (53.2% vs 11.7% for placebo) and (12.5% vs 5,5% for placebo) respectively. These adverse events are often ‘self-limiting’ with gradual

dose titration (Nathan et al., 2006). According to Skidmore-Roth (2015), metformin carries a "black boxed warning" from the FDA for its association with lactic acidosis. Lactic acidosis is a rare condition that affects, on average, six cases per 100,000 patient years of therapy; however, it is fatal fifty percent of the time (Skidmore-Roth, 2015). Metformin is contraindicated in those patients with end stage renal disease due to their inability to metabolize and eliminate the medication from the body (Friedhoff, 2009; Skidmore-Roth, 2015). To further explain, the hepatic system does not metabolize metformin, it is excreted from the body unaltered completely by the renal system. If the renal system is impaired, the drug is not processed properly and acidosis is produced as the drug accumulates within the body. Some people that have been diagnosed with type II diabetes, especially the elderly population, have diminished renal functioning and is often unable to take metformin due to this risk of acidosis (Mokdad et al., 2001). Potential metformin users should have their renal function study tests completed before therapy is ordered and annually thereafter (Skidmore-Roth, 2015). It is also recommended that when x-rays with contrast dyes are ordered, the patient on metformin therapy should discontinue the therapy before the test is initiated and therapy should only be restarted after kidney function has proven to be within normal limits (Skidmore-Roth, 2015). Even though metformin is not processed through the hepatic system, it is not recommended for the patient with chronic liver disease or for those patients who are heavy drinkers of alcohol, due to the possibility of the accumulation of lactic acidosis (Skidmore-Roth, 2015). Metformin is also contraindicated in patients with the following conditions: congestive heart failure, low blood pressure or other disorders pertaining to a

reduction in tissue perfusion and metabolic acidosis (including diabetic ketoacidosis) (Skidmore-Roth, 2015).

Another class of medications used to treat type II diabetes is known as the thiazolidinediones, also known as TZD's. The medications in this group, also called glitazones, include rosiglitazone (Avandia) and pioglitazone (Actos). These medications were approved by the FDA to treat type II diabetes in 1999 . These agents treat type II diabetes by increasing insulin sensitivity within the body by acting on the patient's muscles, fat and the liver through a process of binding (Skidmore-Roth, 2015). By improving insulin sensitivity, the body is able to treat a stubborn condition known as insulin resistance via enhancing the body's response to insulin by increasing the reuptake of glucose by the peripheral tissues and a reduction in hepatic glucose production (Skidmore-Roth, 2015). In due course, the TZDs produce their glucose-lowering effects by increasing insulin sensitivity in the muscles, fat and liver rather than by stimulating insulin secretion and ultimately the TZD does not stimulate insulin production from the kidneys (Inzucchi, et al., 2012). Due to the mechanism of action, an episode of hypoglycemia is highly unlikely and the genetic changes within the cells of the targeted tissues may take several weeks in order to reveal efficacy (Skidmore-Roth, 2015). These agents are indicated to be used in conjunction with a reduced caloric intake and increased physical activity along with a SU, metformin and or insulin therapy. This category of medication can be implemented as second line therapy and is a viable option for patients who are diagnosed with insulin resistance or renal disease (Nathan, 2006; Inzucchi, et al., 2012).

The advantages of TZDs include their ability to decrease the A1C with a reduced risk of hypoglycemia. There is also evidence of an improvement of the lipid profiles with a simplified dosing schedule. To further explain, primary advantage of TZDs include their relative efficacy when compared to other agents in the market (A1C levels are reduced an average of 0.5% - 1.4%) and their low risk of hypoglycemia (e.g., 0.6% incidence in patients taking rosiglitazone vs 0.2% in patients taking placebo and 5.9% in patients taking SUs.) (Nathan et al, 2006). As mentioned earlier, it may take several weeks for the efficacy of TZDs to be evident. TZDs also offer the advantage of controlling blood glucose without increasing circulating insulin levels and without inducing hypoglycemia when used as monotherapy (Powers, 2005; Nathan et al., 2006). Pioglitazone has a positive effect on lipid metabolism. To be precise, it decreased triglyceride levels by up to 26% and increased HDL cholesterol levels by up to 13% but did not increase LDL cholesterol in clinical trials (Edwards et al., 2008; Nathan et al, 2006). Consequently, pioglitazone may improve the LDL/HDL ratio (a predictor of cardiovascular risk). Nathan et al. (2006) contends that this improvement in lipid metabolism is not evident with rosiglitazone.

Rosiglitazone is administered every day or twice daily with a maximum daily dose of 8 mg. Pioglitazone is administered every day, with a maximum daily dose of 45 mg. Both TZDs should be titrated gradually in an effort to monitor for adverse events related to fluid retention. They can be administered with or without food (Skidmore-Roth, 2015).

There are some limitations to the TZD class as well. Nathan et al. (2006) identifies these limitations as exacerbating cardiovascular issues, fluid build-up in the body (edema), increase in body weight, potential interaction with certain drugs and medication cost. One of the most disturbing adverse events associated with TZDs include edema (fluid retention) and dose-dependent weight gain {ranging from two (2) to seven (7) pounds and two (2) to six (6) pounds} for rosiglitazone and pioglitazone, respectively (Powers, 2005). The prescribing information for both TZD's has boxed warnings emphasizing the increased risk of developing or worsening cardiovascular conditions. These agents are contraindicated in patients with New York Heart Association Class III or IV heart failure, and TZDs can worsen heart failure regardless of severity. In addition, TZDs have been associated with the development of new onset heart failure in some patients (Skidmore-Roth, 2015).

Studies, in fact meta-analysis studies, reveal that there is an association of cardiovascular events and the use of rosiglitazone – especially as it pertains to heart attacks and other cardiovascular events when compared to other pharmacological treatments for type II diabetes (Lincoff, 2007, p. 1185-1186). Asnani et al. (2003) contends there are some slight differences in the two medications identified within the class of TZD. Goldberg et al (2005) concurs as this comparison study reveals a difference in lipid profiles between these two agents. This comparison study of patients with type II diabetes and dyslipidemia (lipid imbalances) assessed the treatment with pioglitazone or rosiglitazone for 24 weeks. At the end of the study, triglyceride levels significantly decreased (-12.0%) in the group taking pioglitazone and increased (+14.9%) in the group taking rosiglitazone. Additionally, the group

taking pioglitazone experienced a more significant increase in HDL levels compared to the group taking rosiglitazone. Additionally, the group taking pioglitazone experienced a more significant increase in HDL levels compared to the group taking rosiglitazone (14.9% vs 7.8%, respectively; $p<0.001$) and a much smaller increase in LDL levels compared to the group taking rosiglitazone (15.7% vs 23.3%, respectively; $p <0.001$) (Goldberg et al., 2005).

Friedhoff (2009) identifies the rigorous process that the pharmaceutical company has to endure in order to bring an agent to market and the role the FDA takes to ensure the American public remains safe with these drugs on the market. It is uncertain whether or not these differences on the lipid profiles influence the various cardiovascular outcomes observed between the two TZDs. However, it should be noted that the FDA mandated a boxed warning stating the increasing CV concerns (including myocardial ischemia) with rosiglitazone (Skidmore-Roth, 2015). Other warnings associated with TZDs include an increased risk of myocardial ischemia (as part of the rosiglitazone boxed warning) and, in female patients, bone fractures (Nathan et al., 2006; Skidmore-Roth, 2015). Powers (2005) reveal that hepatic toxicity is another concern with this TZD class; therefore, their use in any patient with liver failure is contraindicated. This concern was primarily with an earlier TZD, troglitazone. Troglitazone was withdrawn from the American market in the year 2000 due to its association with hepatic toxicities. Liver function studies should be monitored with the current agents. Monitoring lab values and the increased nominal cost of these agents can be costly to the patient who has been prescribed TZD therapy. The current ADA consensus guidelines endorse the use of TZDs as a

second or third-line add-on therapy option for patients on metformin. The AACE guidelines endorse the use of TZDs as an option but they discuss the increased concern of CV risks with rosiglitazone (Nathan et al, 2006; AACE, 2007).

Alpha-glucosidase inhibitors (AGIs) are another group of oral antidiabetic agents that lower blood glucose levels by blocking the breakdown of carbohydrates in the small intestine, which in turn prolongs the absorption of blood glucose in the body. Acarbose (Precose) and miglitol (Glyset) are members of the AGI class of drugs. Acarbose received FDA approval in 1995, and miglitol received approval in 1996. AGI's are indicated for monotherapy as an adjunct to a reduced calorie diet and exercise to lower blood glucose levels. Acarbose has an indication to be prescribed with a SU, Glucophage (metformin) or insulin therapy. Miglitol is indicated for use in combination with a SU (McCann, 2007). Elevated postprandial glucose levels are often times a challenge for the type II diabetic patient. AGI's are particularly appealing to the patient who experiences elevated post-prandial glucose levels; however, the gastrointestinal adverse events make them a bit less attractive to the consumer (McCann, 2007). The postprandial rise in blood glucose may be a significant problem for many patients with type II diabetes and monotherapy with acarbose or miglitol may be beneficial in these types of patients (McCann, 2007).

The mechanism of action of the AGI category of medication is established within the gastrointestinal tract. Asnani et al. (2003) contends that these medications decrease the absorption of carbohydrates, which by the way is the source of dietary sugars, in the intestinal tract. This process is mechanism of action begins when within thirty minutes of ingestion. This medication binds and prevents the enzymes,

alpha-amylases and alpha-glucosidases, from breaking down carbohydrates in the small intestines. Preventing this molecular process decreases the possibility elevated post-prandial glucose levels (McCann, 2007). For maximum effect of this pharmaceutical agent, it must be ingested before the meal is consumed.

The main advantages of AGIs include that it is not associated with hypoglycemic episodes nor is it associated with an increase in body weight (McCann, 2007). As mentioned earlier, the mechanism of action of acarbose is in the GI (gastrointestinal) tract. A small portion of acarbose, about two percent, is actually absorbed into the body via the bloodstream. This is a favorable attribute of this class of medication because it also has a diminutive opportunity to interact with other pharmaceutical agents. However, it is important to note that acarbose may affect the absorption of the popular medication, digoxin. An increase dose of digoxin may be necessary, as it has been proven to affect the bioavailability of the drug (McCann, 2007; Nathan, 2006). Over fifty percent of the unabsorbed medication is excreted in the feces (Nathan, 2006). On the other hand, a 25-mg dose of miglitol is entirely absorbed and over 50% of a 100-mg dose is absorbed, but there is no evidence of any therapeutic effect of miglitol outside the GI tract. This agent has an elimination half-life of about 120 minutes and is processed entirely by the urinary tract. Caution should be taken when prescribing these agents with medications such as glyburide, metformin, ranitidine, and propranolol. Caution should be used because decreased peak plasma concentrations and drug absorption values are noted when they are taken concomitantly (Nathan, 2006).

The limitations of this class of medication hinges on the poor efficacy rating, gastrointestinal disturbances, dosing and cost. The expected A1C reduction is 0.5% to 0.8% and the most common side effects are gastrointestinal related such gas, bloating, diarrhea and abdominal discomfort (Nathan, 2006). These gastrointestinal adverse events are usually self-limiting and the causative factor is related to the undigested carbohydrates remaining in the large intestines. These carbohydrates combine with intestinal bacteria and the process of fermentation cause the gastrointestinal disturbances (Nathan et al., 2006). The dosing of AGI's can be a bit inconvenient, as they should be administered three times a day at mealtimes. In fact, it is recommended that both agents be initiated at 75 mg/day (25 mg TID) and, if necessary, titrated to a maximum daily dose of 300 mg (100 mg TID). A gradual escalation schedule is recommended to decrease the chances of gastrointestinal disturbances. As expected, with the type of mechanism of action of the AGIs, these agents are not indicated to be used as a treatment regimen for patients who have intestinal-related disorders dealing with the breakdown or the absorption of food particles. These agents are also not indicated for patients diagnosed with diabetic ketoacidosis or end stage renal disease. Interestingly, miglitol has not been reported to have issues with the hepatic system; however, acarbose is contraindicated with patients with hepatic disorders. Nathan et al. (2006) reveals that elevated doses of acarbose in the body may cause an elevation of liver enzymes. In clinical trials of acarbose, 6% of patients had liver enzyme levels more than 1.8 times normal, as opposed to 2% in the placebo group, but these elevated levels created no symptoms and were not associated with any liver dysfunction (Fisher et al., 1998). When

acarbose therapy is prescribed, liver enzyme levels should be monitored quarterly during the first year of therapy (Coniff et al,.1995).

In the event of a hypoglycemic episode during AGI therapy, Fisher et al (1998) recommend oral glucose tablets because sucrose will not be effective in raising the blood glucose level because its absorption would be blocked by the effects of AGI therapy.

The ADA consensus guidelines do not endorse the use of AGIs; however, the AACE guidelines endorse their use only as an option in patients with modest elevations in A1C (Nathan et al., 2006; AACE, 2007).

Incretin-based therapies target the incretin system in the body. In incretin-based therapy, these pharmaceutical agents affect the incretin hormone, GLP-1 (glucagon-like peptide-1). GLP-1 is a hormone produced in the intestines and is responsible for the regulation of glucose following the digestion of food. At the time of this study, two types of incretin-based therapies are currently available in the US, GLP-1 analogues and DDP4 (dipeptidyl peptidase-4) inhibitors.

The GLP-1 receptor agonists are designed to treat type II diabetes by mimicking the endogenous GLP-1 profile. This class of medication reduces the A1C, on average by 0.8% to 1.6%. (Nathan et al., 2006; Skidmore-Roth, 2015). GLP-1 therapy can be used in conjunction with metformin, SU's, TZD's or basal insulin (Skidmore-Roth, 2015).

The mechanism of action for the GLP-1 class of agents is based on mimicking the effects of the endogenous GLP-1 profile. Skidmore-Roth (2015) contends that this class of medication binds to the GLP-1 receptor site within the pancreatic beta and

stimulates insulin in a glucose-dependent manner. It subdues glucagon production from the liver while delaying gastric emptying creating a sense of fullness (Skidmore-Roth, 2015; Nathan et al., 2006). According to Wajchenberg (2007), this class of medication shows promising evidence of a possibility of preserving beta-cell function. Data from studies involving rodent physiology suggest that in addition to normalizing the blood sugars, this category of medication may preserve the beta cells as well as increase their production. The proliferation of beta cells is a key factor in maintaining a healthy pancreas for humans.

GLP-1 is a hormone that is naturally destroyed by the enzyme dipeptidyl peptidase-4 (DPP-4) and has a half-life of about 60-120 seconds. A GLP-1 agonist is resilient and is not easily degraded by DPP4. In fact, the half-life of manufactured GLP-1 is up to thirteen (13) hours as opposed to natural GLP-1, which is 1-2 minutes (Drucker, 2006; Campbell, 2007).

GLP-1 therapy is provided in a subcutaneous injection and is administered twice or once daily (exenatide and liraglutide, respectively). When GLP-1 therapy is administered in conjunction with a SU, the manufacturer recommends decreasing or discontinuing the SU to lessen the chances of a patient experiencing an episode of hypoglycemia (Skidmore-Roth, 2015).

There are advantages and limitations of GLP-1 therapy. One advantage is GLP-1 treatment is indicated to be used with other regimens in the marketplace to treat diabetes (Nathan, 2006; Amori et al., 2007; Skidmore-Roth, 2015). Due to the mechanism of action, the incidences of hypoglycemic episodes are rare with this class of treatment. Clinical trials have demonstrated the added benefit of weight loss

when GLP-1 therapy is implemented (Amori et. al, 2007; Powers, 2005; Skidmore-Roth, 2015). Studies reveal that type II diabetic patients are often challenged by the issue of weight gain and the effects of weight are of utmost importance when implementing a plan of action for treatment (Unick et al., 2011; Heller, 2004; Mokdad et al., 2001). The limitations of GLP-1 therapy include the adverse event profile, in particular, the gastrointestinal (GI) events. These gastrointestinal events (nausea, vomiting, and diarrhea) are usually self-limiting especially when the titration dosing schedule is executed correctly (Amori et al., 2007). Other limitations include the fact that it is an injection, associated with multiple endocrine neoplasia type II and medullary thyroid carcinoma (boxed warnings for the GLP-1 class of medications) and it is a costly regimen (Skidmore-Roth, 2015).

The DPP-4 (dipeptidyl peptidase-4) Inhibitor is a class of medication available in the United States to treat type II diabetes. A DPP-4 inhibitor can be used as monotherapy or in combination with other agents such as metformin, TZD, SU, and/ or basal insulin (Campbell, 2007; Hollander et al., 2011).

The mechanism of action for the DPP-4 inhibitor is to impede the actions of the enzyme DPP-4, which is designed to degrade the body's endogenous GLP-1. It is important to keep GLP-1 circulating because its natural job is to normalize blood glucose levels by preventing hyperglycemia (Hollander et al., 2011; AACE, 2007). Hermansen (2007) contends that there is evidence of this class of medication prolonging the activity of incretins and inadvertently naturally preserving beta-cell function. To further explain, when beta cells are preserved it allows the pancreas to continue to secrete the life- saving hormone, insulin. As the pancreas continues to

secrete its own insulin there is less chance of needing exogenous insulin due to pancreatic cell burnout.

The mechanism of action has revealed a unique method of regulating blood sugar levels that are independent of pancreatic stimulation; therefore patients with a history of hypoglycemic episodes or those who have challenges with weight should be considered for therapy with a DPP-4 inhibitor (Inzucchi et al., 2012). According to Inzucchi et al,. (2012), national guidelines in the United States have recommend medications within the class of DPP-4 as second-line therapy for type II diabetes. The DPP-4 inhibitor class of medication can be administered with or without food and is dosed once a day. The manufacturer recommends if the patient has been diagnosed with renal insufficiency, the dosage of the medication should be altered to a reduced dose to prevent further renal insufficiencies (Inzucchi et al., 2012). There are advantages and limitations to DPP-4 therapy. Studies reveal that A1C reduction is moderate when used as monotherapy. The A1C is lowered by 0.7% to 0.9% and the fasting plasma glucose as well as the post-prandial glucose levels is significantly lowered when compared to placebo (Inzucchi et al., 2012). Comparison studies with the SU group reveal not only a decrease in the aforementioned parameters but there was a significant decrease in the body weight as well whereas the SU group identified a weight gain (Inzucchi et al., 2012). With the once daily dosing of this oral medication, a weight neutrality status and a low side-effect profile (as it relates to GI disturbances and hypoglycemic episodes) makes this agent desirable for the type II diabetic who desires glycemic control (Skidmore-Roth,

2015). The limitations of the DPP-4 class include the increased cost (as compared to older agents) and the increased incidences of pancreatitis (Inzucchi, et al., 2012).

Amylin-based therapy (Amylinomimetics) is identified as a treatment option for type I or type II diabetes. Nathan et al. (2006), reveals the efficacy as being moderate. When this agent is administered in conjunction with mealtime insulin therapy, the average A1C level is decreased by 0.5 to 0.7%. Pramlintide (Symlin) is an injectable agent, has a mechanism of action that enhanced body's own glucose metabolism and insulin sensitivity. It does this by mimicking the effects of the endogenous GI hormone, amylin. Amylin is a hormone created by the beta cells in the pancreas. These small peptide hormones are designed to normalize blood glucose production by decreasing gastric emptying, creating a sense of satiety and decreasing glucagon production (Skidmore-Roth, 2015). This is a key factor in not only controlling the post-prandial glucose levels but suppressing the appetite as well. According to Skidmore-Roth (2015), in comparison to other blood-glucose lowering agent, pramlintide demonstrates more of a correlation to the steadiness of the post-prandial glucose levels as well as the amount of insulin circulating within the body. This is important because the amount of this circulating hormone, insulin, in the body has a direct correlation to increased incidences of weight gain (Heller, 2004). In fact, due to this diminished requirement for insulin therapy, this class of medication is associated with weight loss. There are higher incidences of hypoglycemia when the medication is administered with insulin therapy. Many patients are unwilling to adhere to the therapy due to the two separate injections required to maximize therapy. The product is prescribed to be administered simultaneously with injectable insulin

therapy. If administered before meals, their insulin dosage must be reduced by fifty percent to decrease the chances of a hypoglycemic episode (Skidmore-Roth, 2015). Compliance is often an issue as this medication due to timing. This medication should not be administered after the meal has been ingested. The dosing regimen is escalated at intervals of a week to two weeks. The duration is individualized to the patient – either the patient meets the goal of good glycemic control or unable to tolerate the therapy due to gastrointestinal adverse events, such as nausea. The prescribing information instructs the patient to omit the dose in the event that the patient "forgot". The medication should be postponed until the following day of therapy. Type I diabetic patients generally are prescribed more of this category of medication than the type II diabetic patient. The administration site is a concern as well. The subcutaneous tissue in the thigh or abdominal area is permissible however the posterior area of the upper arm is not recommended due to insufficient blood stream absorption (Skidmore-Roth, 2015). The prescribing information for Pramlintide suggests never mixing insulin in the same syringe because of the decrease predictability of the product when mixed. It is also recommended to administer the medication within two (2) inches of the insulin site of injection (Skidmore-Roth, 2015). The ADA (2017) guidelines do not recommend Pramlintide as a therapeutic agent for the treatment of type II diabetes. In fact, AACE guidelines recommend this as a therapeutic agent only as an addition to insulin users who seek a "moderate" reduction in their A1C (Nathan et al., 2006).

There are some advantages and limitations associated with this class of medication. The advantages include potential weight loss and (possible) reduction in

their total daily dose of insulin (Nathan et al., 2006). The limitations include the following: injectable therapy, limited effectiveness of the agent, complicated dosing with multiple injections required, costly and there is a high incidence of gastrointestinal disturbances (Inzucchi, et al., 2012).

In summary, this doctoral thesis identifies six categories of medication to treat type II diabetes. The healthcare providers have an armamentarium of treatment regimens for this chronic disease, diabetes. These available choices allow the provider to choose the regimen most appropriate for the patient albeit, efficacy, safety or cost. Creating a *knowing organization* allows all stakeholders involved in caring for patient with a chronic disease, such as diabetes, to be aware of every component surrounding the treatment regimen (Choo, 2006). This added knowledge equates for a more informed decision.

2.4 Theoretical Framework

The theoretical framework implemented for this action – learning based research can be identified as a blend of two theories. The initial theory is a blend of organizational theory and information science. This theory is identified as Choo's *knowing organization*. The framework of Choo's *knowing organization* (Choo, 2006) postulates that advancing education and critical thinking through "sense making, knowledge creation and decision-making" can be accomplished with collaborative efforts and shared visions among stakeholders within the organization (Choo & Johnson, 2003). The second theory is identified as Simon's *bounded rationality theory*. This decision-making theory is based on economic science.

To begin with, in order to address the cost crisis within the organizational healthcare arena, stakeholders within the industry must have evidenced-based data in order to formulate cost-effective decisions. Stakeholders must be able to make sense of the environment within the healthcare system, create knowledge through evidenced based data and make sound decisions through this information gathering process (Choo, 2002). Within this action learning process, this can be accomplished due to the authenticity involved in the political dynamics of this workplace problem. Each of the components identified as sense-making, knowledge creation and decision-making has its own distinct value as it pertains to organizational management. However, Choo (1998) contends that it is the interconnection of these components that create a true '*knowing organization'*. According to Thorpe and Holt (2008), sense-making can be defined simply as making something sensible. The concepts involved in the sense-making experience deals with individuals reviewing various conditions while simultaneously making sense of the experience. These communal thoughts of the stakeholders are linked together to structure the purpose of the organization and to actually frame the problem(s) identified within the organization (Choo, 2002). When workplace problems are discovered, they often become a platform to create knowledge in order to make sound decisions. In the healthcare arena, there are three types of knowledge: implied knowledge that is often implanted through years of experience; formal knowledge formulated through education, rules and regulation; and cultural knowledge communicated via one's own personal traditions, principles and standards. In order to create new knowledge there has to be an interconnection of conversion, collaboration and amalgamation of all forms of

organizational knowledge (Choo & Johnson, 2003). The overall goal of knowledge creation is to generate innovative ideas in order to expand an organization's level of capability. These ideas create sensible interventions that often set forth a plan of action with new alternatives. Choo (1998) contends that these new action plans will often times create well-orchestrated successes; however, there may also be hidden challenges as the plan unfolds. Albeit a challenge or a success, when the interventions are implemented a decision is forth-coming. To further explain, when these innovative ideas are presented with evidence-based data, the interventions are implemented and a decision is created. Through this decision-making process, an organization is able to give birth to new beginnings (Choo, 2002). Decision-making can be defined as a component within organizational management that is goal-driven and structured by the preferred rules and regulations of the organization (Thorpe & Holt, 2008). The organization has an ability to grow and allow others to learn from not only the successes but the challenges as well.

Sense making, knowledge creation and decision-making are indeed key components to constructing a "knowing organization" (Choo, 1998; Choo, 2006). This theoretical framework was selected for this action – learning based research because its implementation creates an authentic educational evaluation of organizational management. It also illustrates an insightful and collaborative approach for the stakeholders involved in the process of action learning (Herr & Anderson, 2005). This type of framework is ideal when addressing America's complex healthcare crisis (Choo, 2002).

2.4.1 Sense Making

Weick (1979) uses sense making as a descriptive term to identify how individuals within an organization perform in an environment by linking their experiences using critical thinking to generate knowledge. Sense making is often triggered by a challenge in the organization that has caused some sort of disruption or concern to the stakeholders within the organization (Weick, 1995). These disruptions or concerns offer opportunities within the organization to create new knowledge. Weick (1995) contends that there is a formula used to identify these disruptions and concerns – discovery, choice and retaining. In the discovery phase, the stakeholders review the disruptions or concerns and try to "make sense" of these issues. This selection process is usually based on the "cause and effect" methodology. This type of explanation is clear with meaning for the stakeholders. The data collected is reviewed and a choice is made by using past or present interventions that have been successful. If using past or present interventions are not effective, new ideas are generated. A selection is then made from these choices and the solution is retained and implemented. Upon further evaluation, the solution is captured as a success or perhaps a "challenge" for further study.

Organizational sense making as it relates to healthcare is primarily maneuvered by the political beliefs and / or actions of the stakeholders within industry (Austvoll – Dahlgren et al., 2008). When a *political driven belief* is an intricate part of the equation, data driven evidence is beneficial to create a more plausible structure to the process. Stakeholders may implement their political beliefs as a method to direct their choices of the various interpretations concerning choices identified in America's

costly healthcare dilemma. In an *action driven process*, the stakeholder may review the past and present actions within the healthcare environment to give meaning to their structure of sense-making. In this sense-making process of healthcare, the stakeholders develop grounds of significance in order to validate the choices in which they have committed themselves – especially when billions of dollars are at stake (Poisal et al., 2007; Kahn & Anderson, 2009).

2.4.2 Knowledge Creation

According to Choo (1998), knowledge creating is often ignited by a detectable void within the current knowledge of an organization. When these voids in knowledge are not properly addressed, they often impede solutions to work place problems and will hinder the opportunity for organizational growth (Choo, 1998; Choo, 2002). The literature reveals that there are three categories of knowledge (Choo & Johnson, 2003; Choo, 2002). To begin with, *implied knowledge* is naturally developed after years of experience and tutelage – this pertains to an individual or group. Secondly, *formal knowledge* is formulated through education, organizational rules and regulations, policies and procedures, etc. Finally, *cultural knowledge* is communicated via one's own personal traditions, principles and/or standards. It is through time filled teachable moments that implied, formal and cultural knowledge amalgamate in order to form organizational core competencies. Organizational core competencies provide the organizations with unique structure and are often attached to the values and norms of the stakeholders (Choo, 1998).

It is important that organizational core competencies remain refreshed with new ideas to prevent stagnation (Choo, 1998). To further reiterate this point, Leonard (1995) reveals four behaviors associated with successful organizations. These behaviors are identified as follows: shared best practices and thought provoking ideas, utilizing integrated technologies and tools to enhance these new ideas, implementing these new ideas while thoroughly documenting the challenges as well as the successes. It is dutifully noted that these behaviors were implemented while collaboratively seeking the guidance of those stakeholders who share an interest outside of the organization. When stakeholders from outside of the organization are invited to be involved in the problem-solving efforts, new perspectives are often generated. Even though innovative solutions can be formulated, tension may also arise (Leonard, 1995). In this case when implementing the new methods, it is crucial that the new practices are adaptable to the existing organization. Implementing the new solution into the workplace is the responsibility of all stakeholders involved in the process (Leonard, 1995).

When new ideas concerning the American public healthcare system are being implemented, there are a couple of behaviors that are vital to the success of the execution of this process (Leonard, 1995). To begin with, the healthcare system is formulated with governmental rules, regulations and standards. The stakeholders must be receptive to the new ideas as they incorporate their level of expertise in various areas of the process. Secondly, since stakeholders are identified from various departments within the system i.e. healthcare providers, managed care divisions, pharmaceutical companies, insurers, consumers, pharmacies, etc., it is imperative that

all disciplines be properly informed of the objectives within the process. To be certain that this behavior is executed Leonard (1995) highlights the importance of constant collaboration. When the objectives are revealed and all of the stakeholders are in agreeance, these innovative ideas build knowledge and are capable of facilitating learning within appropriate healthcare organizations.

2.4.3 Decision Making

The decision making process in organizational management is designed to discover various courses of action for the purpose of goal-attainment (Easterby – Smith et al., 2008). In this stage of creating a "*knowing*" organization, the challenge is often surrounded by issues of ambiguity when faced with choosing appropriate interventions to solve the problem. Decision making in the dynamics of organizational management involve two features: clearly defined goals and clearly defined interventions (March & Simon, 1993). When the stakeholders understand the goals as well as the interventions, the decision making process is usually guided by the decision principles and practices within the organization. Having this sense of clarity defines the criteria to be reviewed, as well as the interventions to be considered. Relevant information is easily detected among the stakeholders, as they are familiar with the components within the selection process. According to March and Simon (1993), choosing the appropriate interventions is simplified with episodes of familiarity and single goal – attainment. On the other hand, when goals are clear and the interventions are not clear, there is a course of action necessary in order to create success. Mintzberg, Raisinghani and Theoret (1976) have identified a course

of action that entails three components in order to create success in this decision - making process. They are as follows: *identification, development and selection.* The course of action involving *identification* allows the stakeholders to accept the fact that there is indeed a problem and understand the need to address the issue. The course of action involving *development* allows the stakeholders to review viable options and create a solution. The course of action involving *selection* concentrates on choosing the intervention(s) with the least path of resistance and the greatest potential for stakeholder commitment.

In the event that there are large groups of stakeholders and the decision making process involves conflicting goals yet everyone is clear on the preferred interventions – the organization must behave as a coalition (Cohen, March & Olsen, 1972). In other words, alliances are formed in order to endorse preferred interventions. Large organizations encountering confusion concerning goal-attainment will often adhere to the rules and regulations of the organization (Starkey et al., 2009). The stakeholders involved will often create discussion groups and formal procedures that permit everyone with a vested interest identify their concerns, make inquiries, validate points and reach a sustainable conclusion. This decision-making process creates a conclusion that is sustainable because it has been properly formulated through negotiating and compromising (Cohen, March & Olsen, 1972).

In situations whereas there is little clarity on both goal attainment and interventions, Cohen, March and Olsen (1972) have identified an approach known as the "garbage can" approach. With this approach, brainstorming is implemented in order to identify organizational challenges, viable solutions, stakeholder involvement

as well as evaluation tactics. During this process, the challenges are identified and viable solutions are paired with them. The availability of stakeholders is then reviewed in order to identify who has the time, energy and effort to commit to execute the plan of action.

When creating a "knowing" organization, many of the aforementioned decision- making methods are implemented contingent on circumstance (Choo, 2002). When a group of stakeholders within an organization has been equipped with the information necessary to identify goals and interventions to create practical solutions, this is often noted as a well-structured situation (March & Simon, 1993). In the event that the goals are not clear and the interventions are not, the phased process of searches with rules and regulations being the foundation of the search has proven to be effective – especially in large groups (Cohen, March & Olsen, 1972). Positioning the rules and regulations of the organization as the foundation acknowledges acceptable interventions without parochialism or uncertainty. Finally, in situations where total perplexity has been identified, brainstorming is a practical process. Brainstorming allows the group to identify challenges, seek solutions and assign a plan of action to the most qualified stakeholder who has the time, energy and effort to complete the task (Cohen, March & Olsen, 1972).

2.4.4 The Knowing Organization

When creating a "knowing" organization, a constant exchange of relative information is imperative for growth and opportunity (Choo, 2002). In fact, the

organization should be designed to allow a continuous flow of information through the links of sense-making, knowledge creating and decision making.

Choo (2002) contends that during the process of sense making, a void within the organization is often discovered. When the void has been identified, its origin and its impact should be sought out immediately. The end-product of sense making is the stakeholder's view of the void and the suspected impact that this void has on the organization. Through various collaboration efforts goals are set and the interventions are created to propel the organization in the desired direction of change (Leonard, 1995). As this plan of action is developed and the interventions are set forth, this shared purposeful data allows the stakeholders within the organization to detect the workplace problems and seek the opportunity to create modifications within the system (Choo, 2002). In the event that the stakeholders are unable to pinpoint the origin of the challenges crippling the origination, this is considered a void in the knowledge level of the company. When a void is discovered new knowledge must be created to address this issue; hence the term *knowledge creation*. In the case that stakeholders are familiar the challenge, the organization can proceed with the courses of action to rectify the problem(s) and or challenge(s) (Choo, 2002). This is known as a void in the decision making process. The ultimate end-result of the concept of knowledge creation is advancement of organizational opportunities through innovative ideas. Developing new ideas through the decision making process certainly has the capability of valuable progress; however, there is also the possibility of uncertainty and failure (Leonard, 1995). Uncertainties and failures are an intricate part of risk-taking of the decision making process, especially in endeavors dealing

with management (Reynolds, 1999; Rigg & Trehan, 2008). When the stakeholders create a plan of action, a commitment to the implementation process leads to a goal-directed evaluation (Choo, 2002). Curtin et al. (2006) proclaims that some of the most effective decisions in healthcare have been identified as short-term, goal oriented and attainable. In this case, a prompt evaluation of the return on investment (ROI) can be dutifully noted (Curtin et al., 2006). A swift evaluation allows challenges during the process to be addressed and adaptive long-term goals may then be initiated through new cycles of sense making, knowledge creation and decision making (Choo, 1998).

2.4.5 Herbert Simon's *Bounded Rationality Theory*

Herbert Simon's *Bounded Rationality Theory* is a behavioral theory approach to decision-making (Simon, 1990). To further explain, this behavioral theory approach is based on a philosophy of behaviorism. In the philosophy of behaviorism, administration is considered a science, a social science to be exact. Behavior science subjects actually deal with the behavior of people and is based on the assumption that there is value in the decision-making process (Simon, 1990; Kalantari, 2010).

Herbert Simon's *Bounded Rationality Theory* takes behavior science a step further. This social science foundation has been grounded within a concept of economic science and in turn it is directly associated with human behavior in the administrative setting (Barros, 2010). This decision-making theory is ideal for the workplace problem identified in this doctoral dissertation. It is ideal because according to Simon (1990) stakeholders within an industry can be rational in their decision-making only

within the boundary of the resources available. These resources may include, but not limited to, personal experiences, written materials of reference and the knowledge of the present action plan. The investigative process of data collection, analyzing factors associated with cost and implementing resources may be available yet time-consuming and expensive (Barros, 2010). Executive leaders within the company may view this as an arduous task in an effort to reach a viable decision for a solution to a company-wide problem. Kalantari (2010) argues that instead of taking the time to complete a thorough investigation, human nature forces those in an organizational management position to take "short cuts". These "short cuts" often transition to what is known as "trial and error" type procedures. This type of problem solving often results in a limited pool of options. Ultimately, this may result in a knowledge deficit with the decision-making processes and objectives cannot be fully accomplished. As a result, the organization embarks upon a concept viewed as "satisficing". Velupillai (2010) explains this concept was created by Simon in the 1950's as a means to achieve the first satisfactory outcome with the available resources at the time of the decision-making process. This process is identified as an ongoing evaluation process. It is known as an ongoing evaluation process because as the steps are implemented and challenges are incurred then the procedure is modified in an effort to promote growth. According to Simon (1990) when there are limited resources, the human brain is prompted to process available resources through what is known as *bureaucratic procedures* executed in previous situations similar to the present problem. In organizational management, stakeholders have a tendency to collaborate in order to create action plans, policies and procedures to develop a

template for continuity (Stacey, 2011). This template, when structured properly can expedite a decision-making process that is acceptable within the organization. Simon's (1990) *Bounded Rationality Theory* explains the process of this decision-making tactic in three stages. The first stage of this process is that of an intelligence activity. In this stage, an authenticated problem must be identified. In this stage, it is crucial to recognize that the problem must not be presumptuous or perceived – as this could result in an erroneous perception of the actual query. When the problem has been authenticated, the next step in the process is the design activity. In this activity, all available alternatives are reviewed in its entirety. Areas of interest within the organization as it relates to these alternatives may include cost, accessibility, practicality as well as data to support the choice(s). The final stage is to select the best alternative(s). This decision-making process does not always result in one hundred percent (100%) rationality (Barros, 2010; Simon, 1990; Kalantari, 2010). However, the outcomes of the process can create a valuable document through the creation of a template. When structured properly, through an ongoing evaluation process, this template can expedite a decision that is not only acceptable but can be implemented and altered as changes within the organization are detected. An ongoing evaluation is often chosen by administration because it allows the company to be strengthened through the challenges (Carmeli & Schaubroeck, 2008; Simon, 1990). To clarify, when a challenge is discovered, a new solution is researched and the template is changed. Ultimately, this type of evaluation creates an organization that can be improved through challenges. Simon's theory of *bounded rationality* has been implemented to create actionable knowledge for the workplace problem

identified within this study, In this conceptual framework, a standard pattern of behavior can be adopted, analyzed and verified by not only an organization but an industry as well (Barros, 2010).

Simon's *Bounded Rationality Theory* applies well to aid in problem-solving through algorithmic procedures (Barros, 2010). This method of strategizing in the arena of decision-making is beneficial because it involves researching the problem, creating valuable objectives (known as criteria) as well as a thorough review of valuable options for a satisfactory outcome (Kalantari, 2010). This theory examines economic constraints and reviews the complexity in its entirety. In the pharmaceutical industry, this is important because such recognition aids in not only the ability to handle the problem at an organizational level but transition it to a frame of reference for an industry problem as well. Case in point, this investigation within this pharmaceutical industry has revealed limited outcomes based data concerning the cost associated with branded products used to treat of type II diabetes. Simon's *Bounded Rationality Theory* allows one to deal with factual data to derive at an acceptable algorithm to address a work-place problem that is actually an industry wide dilemma (Simon, 1990; Velupillai, 2010). Simon's *Bounded Rationality Theory* was implemented to create an algorithm that can be used as a template to identify interventions acceptable to treat type II diabetes and prevent long term (costly) complications associated with the chronic disease, such as cardiovascular disease.

2.5 Diabetes management goal development

In the United States, guidelines for treating diabetes are produced by ADA (American Diabetes Association), AACE (American Association of Clinical Endocrinologist) and AAFP (American Academy of Family Physicians). The ADA is an organization of scientists, consumers, and healthcare professionals (ADA, 2008). The guidelines for this organization recommend an A1C goal of less than 7% with an ultimate goal of reaching this target without experiencing hypoglycemia. They also recommend keeping the fasting plasma glucose between 70mg/dl and 130 mg/dl and post prandial plasma glucose less than 180mg/dl. The AACE membership is usually composed of clinical endocrinologist (AACE, 2007). The recommended guidelines are more stringent in efforts of obtaining better blood sugar control. The A1C goals are less than 6.5%. The fasting plasma glucose level has a goal of less than or equal to 110mg/dl and the postprandial plasma glucose goal is less than or equal to 140 mg/dl. The AAFP consists of family practice physicians. This group does not necessarily set blood glucose goals; however, they encourage individualized treatment planning for the patient (AAFP, 2008).

There are actually two studies that are considered to be the gold standards in terms of diabetes management and goal development in the United States (Brownlee et al, 2016). These two studies include the Diabetes Control and Complications Trial (DCCT) Research Group and the UK Prospective Diabetes Study (UKPDS) Group (Brownlee et al., 2016). In the DCCT (1993) trial a comparison study was completed using an intensive insulin regimen versus conventional therapy in type I diabetics. It concluded that patients managed intensively reduced their risk for microvascular

complications by 35 - 70%. Benefits of blood sugar control occurred via evidence of the reduced A1C concluding that this reduction was indeed beneficial. However, the study does indicate that intensive control does lead to more incidents of hypoglycemia and weight gain. The UKDPS (1998) trial was a large trial using type II diabetes patients as subjects. In the study, patients were selected randomly for either the conventional or intensive therapy group. The intensively treated group reduced their A1C to an average of 7.0% compared to 7.9% in the conventional therapy group. This led to decreased microvascular complications and a trend towards a reduction in heart attacks. In addition, implementing stringent guidelines for blood pressure control created a reduction in both micro and macro vascular complications. Once again, as the A1C was lowered incidences of hypoglycemia increased.

2.5.1 Diabetes Management and Cost Effectiveness

Being in the pharmaceutical industry, one must recognize the correlation of scientific investigations and quantifiable measures to support clinical judgment. In this industry, the stakeholders are often scrutinized as this (costly) science is transformed into applications of clinical knowledge. Without this clinical knowledge, the ability of the healthcare providers to decode facts and identify the best treatment for the patient would be non-existent. Making such informed decisions depend on their levels of clinical expertise and ability to apply this knowledge to the most important stakeholder, the patient. Education is a key factor in the decision-making process especially as it is related to cost-effectiveness. This study demonstrates that there are a number of valid investigations that support the

idea of the link between education and cost-effectiveness especially as it relates to chronic illnesses such as diabetes.

Balamurugan et al. (2006) conducted a study of 56 weeks with the implementation of a diabetes education program to diabetic patients who were of low income. In this study, a continuous quality improvement (CQI) type course of action was initiated to evaluate the quantifiable measures and the cost effectiveness of the program. The participants within the program had a decrease in their A1C on average of 0.45% and the recidivism rate for readmissions to the healthcare facilities decreased as well. This study revealed that within a three (3) year period the estimated cost savings of diabetes – related expenses would be four hundred fifteen dollars ($415.00) per person who completed the program. Over a decade, completers of the program were estimated to have a reduction in cardiovascular disease as well as microvascular disorders by twelve (12%) and fifteen (15%) percent – respectively. The utilization of this educational program decreased the use of funds used within this Medicaid program as well.

Christensen et al. (2004) performed a cost analysis of the effectiveness of a diabetes education program. The three month study involved the implementation of a diabetes education course. This assessment included diabetes knowledge regarding various aspects of nutrition and its relationship to a reduction in A1C. This study revealed that as the participants' education level increased , the A1C level decreased by 0.73%, the body mass index (BMI) decreased by 8.82 kg/m2 (P=.000), waist circumference decreased by 1.27in (P=000), hip circumference decreased by 0.6in (P=.000) and waist-to-hip ratio decreased 0.01 (P=.000) . This training on

nourishment and blood sugar control were calculated to reduce the medical costs associated with hospitalizations by ninety four thousand ten dollars ($94.010).

Cranor et al. (2003) conducted a study to evaluate the sustainability of the results after the community-based pharmaceutical care services had been implemented. There were 136 diabetic, self-insured participants who were enrolled in this study. The goal was to determine the results of lab values measuring blood glucose and cholesterol levels after the initiation of a communal program designed to implement pharmaceutical care assistance – five years ago. The education was provided by certified diabetes educators. The lab values were measured after the initiation of this long-term communal program with identified patients. The patients involved in the program were self-insured by a variety of managed care plans. The blood glucose findings revealed a reduction in the A1C as well as the lipid levels in more than 50% of the patients in the study. In fact, the study revealed that the more elevated the A1C at baseline – the more likelihood of improvement was noted. There was a direct correlation between the cost of caring for this study group of patients and the education / knowledge level. It seems that the more educated the patient – the less it cost to care him/her. The study revealed that the average cost to care for these patients decreased by $1200 to $1872 per patient annually (Cranor et al., 2003). For four years (1997-2001), documented days for leave decreased and productivity increased at an estimated $18,000 per year. According to Cranor et al (2003), the employers were convinced that educating workers who have a chronic disorder such as diabetes has a profound effect on direct and indirect medical cost associated with diabetes, sick leave, as well as productivity rates.

Fries and McShane (1998) conducted a comparison study in order to identify the cost-effectiveness of the health education courses in high-risk patients as compared to other patients who were not identified as high risk. The 2586 participants were randomly selected and provided with an assessment form, a letter of consent and educational materials based on the identified high risk disorders identified during the assessment i.e. musculo-skeletal disorders such as arthritis, cardiovascular issues such as elevated blood pressure and endocrine disorders such as diabetes. The assessment also captured whether or not the patient indulged in activities such as smoking. The direct and total cost of the program was assessed to determine the return on investment (ROI). After 180 days, the direct costs for those identified in the high risk group were lessened by $304 versus $87 in the group who were not identified as high risk. Overall the ROI was 6:1 in the high risk group vs 4:1 in the non-high risk group. Implementing an educational program proved to be beneficial in the high risk patient population more so than those who were not identified as high risk.

Garrett and Bluml (2005) performed an analysis of the cost-effectiveness of a community health management program involving 256 diabetic patients. The analysis consisted of an assessment of the clinical benefits, satisfaction and economic measures from the program implemented to these participants who were self-insured. Various levels of care were provided to the participants who were self-insured. The pharmacists provided scheduled pharmaceutical-based discussions. The health care providers performed physical assessments and screenings. The care provided by these identified healthcare professionals included medication consultations, goal

setting, assessments and screenings. The participants reported an overall satisfaction rating of 95.7% of the pharmacists in the study. There was an increase in the amount of screenings performed as well as improvements noted within the cardio-metabolic assessments. The rate of patients accepting the flu vaccine escalated from 52% to 72%. There was in increase in patients completing their eye exams as well – 46% to 82%. The importance of the diabetic foot exam was conveyed which led to an increase of 38% to 80% for the podiatric assessments. Through these educational efforts, the parameters concerning diabetic care improved from 57% to 87%. The average A1C declined from 7.9% to 7.1%. The average low-density lipoprotein cholesterol (LDL-C) declined by nine points (113.4 mg/dL to 104.5 mg/dL). The average systolic blood pressure was reduced by five points (136.2 mm Hg to 131.4 mm Hg). The overall analysis revealed that the cost per patient was actually $918 lower than the projected outcome at the beginning of the study.

Menzin et al (2001) implemented a study, which assessed the influence of adequate blood sugar regulations on diabetic complications (short term in duration) and the cost associated with these complications. In this study, 3294 diabetic patients over the age of 18 were assessed over a period of three years. The study participants were selected and identified according to their hemoglobin A1C levels. The categorized labels were as follows: good control (A1C less than 8%); fair control (A1C less 8%-10%) and poor control (A1C greater than 10%). Nearly 10% of the 2394 patients participating in the study were hospitalized due to short-term complications associated with diabetes. Over the three year period, the rates were as follow for inpatient treatment: good (13 per 100 patients), fair (16 per 100 patients)

and poor (31 per 100 patients). The respective charges were identified as 970 dollars, 1380 dollars and 3040 dollars. The patients identified as being in poor glycemic control were more costly to the healthcare system. Those patients identified as being in good glycemic control saved an average of 400 to 2000 dollars over a three- year period – when compared to the fair and poorly controlled groups.

Rubin et al (1998) conducted a study to determine the cost-effectiveness of an intensive management program on a population of 7000 diabetic patients who were actively treated and monitored through seven managed health care plans. The savings from the implementation of this intensive management program proved to be significant at a gross-adjusted reduction of fifty dollars per member. In-patient admissions to the local healthcare facility decreased by an average of 20%. The study revealed that patients actively enrolled in the program were more likely to follow-up with their healthcare providers for lab work (A1C and cholesterol levels), foot exams and annual eye exams. The overall conclusion reveals that the initiation of such a program leads to not only improvements in the cost associated with diabetes but the clinical outcomes for present and as well as future.

Shetty et al. (2005) conducted a cost analysis assessing the variations in the expenses associated with the differences in the A1C levels of type II diabetic patients. In this study, there were 3121 patients with an A1C targeted level less than or equal to seven percent and 3659 patients who had an A1C greater than or equal to seven percent. Using data that met the criteria for this study, a retrospective database analysis was performed. Managed care organizations across the country provided the laboratory results from its members. Medical and pharmaceutical claims were also

reviewed for this study. These type II diabetics were not provided with any particular interventions but were followed for 52 weeks to determine an analysis of diabetes related costs for the two groups of patients. After the 52 week study was completed, the follow-up period revealed that the diabetes-related costs for the "above-target" group was $1540.00 per patient; whereas, the "at target" group was $1171.00 per patient. The diabetes-related cost for the group of diabetics categorized in the above range group was thirty-two percent higher than the group at a targeted level of seven or less.

Sidorov et al. (2002) performed a retrospective study to determine if the diabetes disease management (DDM) program had any influence on the cost associated with the care of the diabetic patient. The study participants were diagnosed diabetics chosen from the Health Plan Employer Data and Information Set (HEDIS). Of these study participants, 3118 were assigned to the DDM program and 3681 were not assigned to the program. A retrospective-type study was completed comparing the submitted claims of the participants for two years. The primary care visits per year were similar for those enrolled in the program and those not enrolled. The results were 8.4 visits per year vs. 7.8 visits per year patient. The study participants were diagnosed diabetics for the participants enrolled in the DDM program were less among the commercial group as well as the Medicare group. The results were $302.19 (DDM) vs. $525.96 (non-DDM) for the commercial costs and $424.00 (DDM) and $500.37 (non-DDM) for the Medicare group. For those patients enrolled in the DDM group versus the non-DDM group, the cost analysis

revealed a reduction of 21% for the commercial as well as the Medicare group. The mean savings per person/year was $1294.32. This is a statistically significant value and the patents enrolled in the DDM program achieved better measures in the key diabetes HEDIS review and the charges incurred for care was less than the group who were not enrolled in the program.

Testa and Simonson (1998) conducted a 12 week study including 569 employees diagnosed with type II diabetes. This study was designed to assess the loss earnings associated with these employees as it related to the therapeutic levels of their blood sugar ranges. The blood sugar levels were monitored, symptoms were recorded, quality of life (QOL) assessments were conducted and levels on the job efficiency were assessed via journals and surveys. The interventions used in the study included diet and a well - known sulfonylurea called Glipizide. At 12 weeks, labwork (A1C and fasting blood sugar levels) was performed on the study participants. Those employees enrolled in the study who participated in an exercise and sulfonylurea regimen had lower AIC scores, lower fasting blood sugar scores and better productivity ratings vs those who participated in exercise only. Respectively the results are as follow: A1C scores 7.5% vs 9.3%, fasting blood sugar scores 126 vs 168 and productivity ratings 99% vs 87%. These same employees also had less absenteeism, fewer sick days and fewer “light-duty” assignments. Respectively the results are as follow: absenteeism computed to $24 vs $115 per employee per 30 day period; sick days computed to $1539 vs $1843 per 1000 days of work; and These same employees also had less episodes of absenteeism of $2660 vs $4275 per 1000 days of work. Overall absenteeism ratings decreased by one percent vs an increase of

eight percent for the employees whose blood glucose levels were not in therapeutic range. This study concluded that there is certainly a co-relation of good glycemic control and employee level of productivity.

Type II diabetes is a complex disorder. Recognizing the pathophysiology, epidemiological cost factors, FDA approved pharmacological treatments and proper management of the disease process is interconnected to an overall *accurate* cost of treatment. Linking these factors to workplace relativity within this action learning research is crucial in order to investigate the cost savings and health benefits of medications used to treat type II diabetes in Georgia, United States (Morrell, 2008).

The literature reveals that workplace relativity is of extreme importance in the implementation of action learning based research (Pedler, 2008; Newbold, 1982). This latter section of the literature review reveals workplace relativity, action learner relevance with an overview of the researchers profile and an overall evaluation of the process as it pertains to scientific thinking via the investigator as well as the stakeholder.

2.5.2 Evaluating the process via scientific thinking for the stakeholder

As the new healthcare reform has begun, a variety of changes are occurring in the United States. One of the major changes that have developed is the creation of value-based purchasing. There are three concepts surrounding the framework associated with value-based purchasing and they are as follow: quality care measures, open and honest reporting with clarity, and fair reimbursement recognition (Damberg et al., 2010). To begin with, the concept of quality care measures with proper recognition is unable to be executed without proper performance evaluation. According to Cheng

et al. (2013) quality care measures can be assessed amongst various stakeholders within the healthcare industry such as managed care participants, healthcare institutions, healthcare providers as well as manufacturers within the pharmaceutical industry. The concept of quality measures is a patient centered concept that has been designed to create a 'check and balance' type analogy that would support standardized care to individuals in the United States. Creating this 'check and balance' type system encourages accountability within a circle of excellence as it relates to the stakeholders involved in the care of the patient. When this circle of excellence is expected in the patient- centered strategy, everyone recognizes that the care provided will be assessed, measured and the outcomes revealed (Young et al., 2007). Secondly, this level of accountability and transparency is important as the outcomes are publicly distributed and are pertinent in creating the plan of care to the most important individual in this equation, *the consumer*. According to Doherty (2013) this heightened level of accountability is actually considered a motivating factor to provide quality care to the consumer. When the healthcare provider is publicly "graded" on the quality of care provided, managed care organizations and employers are able to access this data. Employers and managed care companies desire the providers who have demonstrated an acceptable quality care performance (Doherty, 2013; Rosenthal et al., 2008). Needless to say, employers and managed care companies (especially Medicare) should have a vested interest in keeping their consumers healthy. Healthy consumers are less costly (direct and indirect) in terms of provider office visit, urgent care visits, labs, missed days of work, medications, procedures, etc. (King et al., 1998). Thirdly, pay-for-performance is a concept that

has been implemented into the healthcare reform. In the United States, this pay-for-performance (also revealed in the literature as fee-for-service reimbursement) can be defined as a concept whereas practitioners are incentivized for keeping their patient healthy instead of ordering various services. Traditionally our healthcare system was designed to "take care of the sick" instead of focusing on a methodology that would encourage health and wellness – especially as it relates to chronic diseases such as high blood pressure and diabetes (King et al., 1998). Lastly, the consumer, as the primary stakeholder, has to be accountable if any of the initiatives identified in the healthcare reform is to be successful. When requesting the consumer to make more informed decisions about lifestyle changes, adherence to a regimen, coaching and guiding, one must consider the motivating factors. Some of these factors may include lower insurance rates for the non-smoker with lab values that are within normal range (Young et al., 2007). As the stakeholders are recognizing the changes that are occurring within our nation due to the cost of healthcare, plans are being implemented across the country designed to decrease the deficit. According to Damberg et al. (2010), value-based purchasing will be a standard used by healthcare providers to quantify, report and get compensated for quality care provided to their patients. Value-based purchasing involves stakeholders such as providers, managed care companies, consumers and the pharmaceutical industries to address the rising costs of healthcare. When quality care is provided on a routine basis by excellent providers, the practice will be rewarded with maximum reimbursement rates within the managed care plan. According to Young et al. (2007), value based purchasing can be used as an effective influence for the healthcare providers as well as the other

stakeholders. There are 26 quality control entities used to measure this value-based purchasing (Rosenthal et al., 2008). These quality control entities included twelve clinically relevant categories that are processed. For example, whether diabetic patients receive quarterly hemoglobin A1C checks); eight clinically coordinated support efforts (such as documented communications between physician, lab staff, nurse or social services); five summaries identifying the patient's outcomes (this entity will consist of 30-day death rates for related conditions that are cardiovascular or respiratory in nature); and one cost-benefit analysis for each payee. When the healthcare providers submit the claims, the reimbursement rates are based on the rankings. This methodology is a novel strategy and even though the system has not been perfect, Young et al. (2007) reports that the quality incentive program is designed to decrease the cost of treatment by rewarding excellent healthcare practices. The governing bodies of healthcare policy has condoned this method of promoting quality care; however, as a stakeholder within the pharmaceutical industry, who has an insight on true cost-benefit analysis of diabetic medications I urge the evaluators of the system to be certain that the outcomes truly reflect quality care. Simply measuring cost does not address the complexity associated with the full ramifications of the disease process and the adverse events associated with the pharmacologic agents. This is especially evident in the review of long-term outcomes associated with various treatment modalities (Damberg et al., 2010; Curtin et al., 2006; Luce, 2005).

As mentioned, value-based purchasing is certainly one method of addressing the escalating cost of healthcare in the United States. It is especially helpful when

addressing at least two of the components associated with these issues. These components include health and wellness tactics as well as short-term savings tactics (Doherty, 2013). According to Cheng et al. (2013) the components dealing with health and wellness are designed to encourage preventive medicine. These often surround programs such as healthy eating, smoking cessation, weight loss, or substance abuse counseling. Implementing preventive measures have been associated with creating and maintaining healthy habits, which impacts the health status of individuals. Studies show that when the consumer is healthy, the quality of life improves and ultimately the workforce is maintained and chronic conditions are improved (King et al., 1998). Allowing these value-based purchasing programs to be implemented has positive effects. It will allow employers to offer these health and wellness programs in an effort to increase job productivity, promote a company's mission statement as well as the triple bottom line as it relates to strengthening all stakeholders involved in the creating an optimal level of wellness (Rosenthal et al., 2008). The other component deals with the short-term savings, which stems from getting compensated for quality service delivered to a population of people who genuinely need care – especially those who have chronic illness (Rosenthal et al., 2008). Rosenthal et al. (2008) contends that healthcare providers focusing on tripartite aspects of care such as quality service, excellent treatment and fair reimbursement viewed by others in the healthcare field as catalysts to promote a true value-based system.

2.5.3 Evaluating our actions through Health Impact Assessments

In the healthcare sector of business, conducting a health impact assessment (HIA) is one method of determining if a certain decision has been effective. These assessments have been conducted on an international level for decades (Harris-Roxas, Villani, Bond, Cave, Divall, Furu, et al., 2012). These reports are thorough as they depict the discoveries, impacts, goal attainments and short-comings of our present plans of care.

In fact, many of these health impact assessments reveal evidence-based data to support the use of certain medications to reduce the risk of many of the cardio-metabolic risk factors that are contributing to the cost associated with chronic disorders such as type II diabetes. These studies reveal the value associated with medications such as SGLT2 inhibitors and GLP1 agonists. These medications have proven to be not only safe but efficacious as it decreases the adverse events often associated with medications used to lower the blood glucose level. As of this date, there are two large health impact studies addressing cardiovascular outcomes as it relates to SGLT2 therapy. The first trial is known as the EMPA-REG OUTCOME (Empagliflozin Cardiovascular Outcome Event Trial in Type II Diabetes Patients-Remove Excess Glucose). According to Kosiborod et al. (2017) there were 7,020 patients enrolled in the study and a significant reduction in the number of major cardiovascular events (MACE) categorized as nonfatal myocardial infarction (MI), nonfatal stroke or cardiovascular (CV) mortality in patients who received the SGLT2 inhibitor as opposed to the placebo. The data gathered for this assessment was on adjudicated claims, electronic medical records and data from national registries.

These type II diabetic patients were randomly selected and a medication regimen of empagliflozin (10mg or 25mg daily) was ordered as a treatment. Compared to placebo, the patients in the empagliflozin group encountered a 14% decrease in the primary (composite) end points of the study, which were identified as cardiovascular death, myocardial infarction or stroke as well as a 32% decrease in the overall mortality rate. These factors also contributed to the 38% decrease in the amount of cardiovascular related deaths noted as well. A secondary endpoint of heart failure hospitalizations was dutifully noted with a decreased by 35%. It is important to recognize that empagliflozin is the only SGLT2 inhibitor that is recognized and approved by the FDA (Food and Drug Administration) to reduce the risk of CV death in adults with type II diabetes and established cardiovascular disease.

The second health impact assessment, known as the CANVAS (Canagliflozin Cardiovascular Assessment Program) programs actually enrolled 10,142 patients of whom 72% had established atherosclerotic cardiovascular disease (ASCVD). The patients were prescribed either a placebo or canagliflozin (100 or 300 mg tablets). The first CANVAS program consisted of 4,330 patients and the second CANVAS-R program consisted of 5,812 patients. The analysis of the two trials revealed a 14% decrease in the primary endpoint of MACE (major cardiovascular events) which consisted of a composite of nonfatal myocardial infarction, nonfatal stroke and cardiovascular death. The results from the CANVAS program revealed a significant 33% decrease in the secondary endpoint of hospitalizations for heart failure.

Kidney disease, as mentioned previously in the literature review, is yet another major concern for those patients who have been diagnosed with the chronic disorder,

type II diabetes. Empagliflozin and canagliflozin are both considered suitable clinical choices as treatment regimens for type II diabetes patients. Studies reveal that not only do the SGLT2 inhibitors slow the progression of kidney disease but it also improved the eGFR (estimated glomerular filtration rate) by at least 40% (Cherney et al., 2017; Neil et al., 2017; Wanner et al., 2016). As mentioned earlier in the section entitled classes of medication used to treat type II diabetes, the SGLT2 inhibitor has a mechanism of action that allows glucose to be excreted via the urine in order to lower the blood glucose level. Vallon and Thomson (2017) contend that this diuretic effect not only rids the body of excess glucose but it promotes weight loss and lowers the systolic blood pressure as well.

The GLP1 receptor agonist is the second category of medication used to treat type II diabetes that has shown benefits for those patients at risk for CV (cardiovascular) events. Those health assessment impact studies measuring cardiovascular outcome usually measure a three (3) point MACE outcome of CV death, nonfatal myocardial infarction (MI) or nonfatal stroke and the LEADER (Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results) trial is no exception. In the LEADER trial 9,340 type II diabetic patients who were clinically diagnosed with ASCVD (81% of the overall total) or patients over the age of 65 who were at risk for ASCVD (19% of the total) were randomly assigned to either the Liraglutide group or the placebo group. The three point MACE outcome of CV death, nonfatal myocardial infarction and nonfatal stroke were decreased by 13% with Liraglutide when compared to placebo. In fact, all of the components of the MACE composite revealed a reduction. Marso et al. (2016) suggest that this may be due to the

reduction in the overall CV deaths within the Liraglutide group. There were no reductions in the heart failure events noted in the LEADER trial. According to the American Diabetes Association (2018), Liraglutide is the only GLP1 that has been approved by the FDA to reduce the risk of MACE in adults with type II diabetes and established cardiovascular disease.

As mentioned earlier, kidney disease is a major concern as it relates to type II diabetes. Liraglutide is in the GLP1 receptor agonist category and the LEADER trial reveals some renal benefits. In fact, the LEADER trial reveals a 26% decrease in the risk of macro-albuminuria. Similar to the SGLT2 inhibitor category, Liraglutide use shows a reduction in the weight, systolic and diastolic blood pressure, waist circumference as well as the total cholesterol panel (le Roux et al. 2017). This reduction in weight and improvement in cardio-metabolic risk factors exemplifies value to the treatment regimen.

Health impact assessments are not only completed in the clinical arena. They are conducted in the communities as well. In fact, Davenport, Mathers and Parry (2006) conducted one of the larger studies in the United Kingdom (primarily in Europe) concerning health impact assessments. This study was implemented through the University of Birmingham and was expanded for eight years. In fact, eighty-eight health impact assessments were reviewed. The decisions created from these assessments impacted not only local level but a regional and national level decisions as well. Health impact assessments, in this case, dealt with public transportation, housing, health and wellness, ecosystems and local industries. The review methods included case studies and surveys. The outcomes of this study indicated that

examining the implementation of policy was crucial to identifying whether the plan of action was successful. Davenport et al. (2006) revealed that communicating with the persons who are responsible for making decisions on an individual basis, instead of in a public forum, was important. Communicating with these decision-makers in private discourages the possibility of group-think. These health impact assessments are most beneficial when they are incorporated into the plan of action upon project initiation (Davenport et al., 2006). Davenport et al. (2006) revealed a number of successes with the decision-makers, policy-developers, timing, methodology implementation tactics as well as reportage capabilities. Decision-makers and stakeholders (both external and internal) communicated well. Sufficient communication allowed the researcher to establish credibility early in the process. Upon reviewing this policy-making process a clear commitment to the collaborative efforts involved in legislature, intervention implementation consistency, evaluations and modifications were obvious. Various levels of supportive areas were discovered by the evidence-based data. With this data, political drivers were revealed resulting in recommendations for the planning process. These recommendations for the planning process were implemented in an "on-going" delivery for advancement. The proper timing of these assessments was another area revealed through this evaluation process. Whether or not the health impact assessment is a success or a failure could really depend upon the timing of the assessment and if it is conducive to the policies and procedures of the company. The methodological aspect the assessment was consistent. A variety of factors were discovered that proved to be impactful. Due to the consistency and adequate communication efforts, the

awareness of organizational concerns and urgencies could be used to as action based solutions to work-place problems. There were a number of negative aspects such as unforeseen staffing issues, timeless and availability of resources.

Wismar, Blau, Ernst and Figueras (2007) conducted a study in Brussels, Belgium at an organization identified as the European Observatory on Health Systems and Policies. Expanding over a four- year period (2002-2006), one hundred fifty eight health impact assessments were performed to determine policy - efficacy in nineteen countries in Europe. The results affected ten local and six national decision-making bodies within various sectors including public transportation, environmental planning, farming communities, factories, building structures as well as food and nutrition. Interviews were conducted with those responsible for making decisions in order to determine the effectiveness of the present policy and procedure(s). There were numerous health impact assessments conducted and the complexity of each project varied. However, it is important to note that there were no cancelations of any health impact assessment due to complexity. The level of efficacy was defined via a four-framework model. The four categories of framework chosen to identify effectiveness included a straightforward framework defined as one that leads to an abrupt change in decision-making. An unspecified framework defined as something that creates a heightened level of awareness; however, a modification of policy is not justified with this choice. Thirdly, an opportunity based framework defined as one that would have resulted in a policy change anyway – if rules and regulations were properly enforced. Finally, ineffectual identifies the framework that results in a health impact assessment being completely disregard in the decision-making process.

Wismar et al. (2007) revealed a number of factors indicating goal attainment. To begin with, discoveries revealed on how to effectively deal with stressors encountered within the community. Factors regarding the amount of time to complete decision-making processes in the community were revealed. The stakeholders who were crucial in the decision-making process within the organization were uncovered. This was a crucial point because it enhanced not only the support of the community but leadership as well. Streamlining the process allowed those important to the decision-making process to be accountable early in the development of the proposal. Effective healthcare systems and the costs associated with them were discovered. Wismar et al. (2007) suggested that efficacy be computed via the assessment of three components. These components included health and wellness efficacy, populace efficacy and societal efficacy. The components of health and wellness included those that encouraged the positive and reject those that proposed a challenge. The component of populace included a thorough assessment of the impact noted on the most vulnerable section of the study population. Societal efficacy integrated the health related concerns in the decision-making process. There were some challenges identified in the study. These included communication efforts with the decision-makers across the country. There were differences of opinions noted especially pertaining to the objectives of the various sectors identified in the study used to measure efficacy.

Bourcier, Charbonneau, Cahill and Dannenberg (2015) conducted a study based in Seattle Washington with an organization called the Group Health Research Institute. The researchers compiled a total of twenty-three U.S. based Health Impact

Assessments, completed during the years 2005-2013, with the sole purpose of measuring the efficacy of the changes implemented within the community. Various segments were assessed including ecosystems, city transport, energy as well as healthcare. The levels of impact were considered to be on a regional and state level. When the Health Impact Assessment reports were reviewed, various disciplines were interviewed including key policy makers, stakeholders and actual HIA team members. A total of one hundred sixty six interviews and one hundred forty four surveys were completed. Forty-eight percent of the policy makers indicated that the HIA's were crucial in their decision making process. These recommended changes were incorporated directly into the action plan. These plans of action affected both policies and community programs. In fact, some of the results revealed that outcomes were beneficial far beyond the outcome date. The results revealed that the working relationships became stronger by the knowledge gained in the process. The collaborative efforts allowed the policy makers and stakeholders to identify commonalities between the health and non-related health entities. Recognizing these differences allowed the stakeholders to participate in the conflict-resolution process with ease. When conflict-resolution is simplified, complex problem solving among the group is not such a tedious task (Gase, Pennotti and Smith, 2013). As the efficacy of these changes within these HIA's were assessed, Bourcier et al. (2015) identify a number of successful attributes. The process allows collaboration between the policy makers and stakeholders. With this type of engagement, key personnel required for each dimension of the process is expedited and a plan of action can be more readily developed with full recommendations. Implementing these

recommendations with the right individuals and at the right time is crucial to program success. Bourcier et al. (2015) identified challenges within this process as well. Reportedly, the researchers miscalculated the amount of time, energy and effort required for a project of this magnitude. Accessibility of the data was more of an arduous task than anticipated. Finally, even though proper collaboration ignited the success of the study, facilitating the engagement between the stakeholders and policy makers required countless hours of strategic planning.

As America undergoes drastic changes in healthcare, Rhodus, Fulk, Autrey, O'Shea and Roth (2013) suggest that the stakeholders and policy-makers evaluate the established strategies in order to determine efficacy. Stakeholders and policy makers are often responsible for the changes and a proper evaluation of plan is needed in order to promote productivity. In the healthcare industry this includes identifying plans of action, screening the present process, identifying productive and non-productive choices, assessing the consequences of continuing poor practices, creating recommendations and reporting those recommendations to pertinent stakeholders and policy makers (Rhodus et al., 2013).

This action based learning research within the pharmaceutical industry provides an opportunity to "break new ground" in a setting that traditionally has been accused of being the culprit in matters concerning the escalating cost of healthcare in the United States (Kantarjian et al., 2013). With this extensive literature review, evaluating healthcare cost and the present interventions seem to be an ideal method to determine if the present plan of action is effective. This action based learning research allows an authentic view of such assessment. With the data presented regarding this

workplace problem, the stakeholders and policy-makers shall grasp a deeper level of understanding of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia (Herr and Anderson, 2005; Pearson and Clair, 1998).

2.6 Summary

The literature review reveals that type II diabetes is a costly and chronic disorder. In fact, the ADA (2013) reveals a total economic cost of diabetes as being approximately $245 billion. Needless to say, this disease is costly not only in monetary expenditure but quality of life for the consumer as well. The medications in the marketplace used to treat diabetes are primarily for adults; however, studies show that children are being diagnosed with type II diabetes at an alarming rate (Boyle et al., 2010). As type II diabetes strikes our youth, so does the complications associated with this chronic disorder. Creating an action plan to address the risk factors that contribute to this disorder is crucial in order to effectively deal with issues (ADA, 2015). One of those risk factors includes weight gain (Carlson & Campbell, 1993). According to Hodgson and Kizior (2014), many of the treatment modalities developed to treat type II diabetes involve weight gain. Nearly eighty percent of the persons diagnosed with type II diabetes are overweight (ADA, 2015). In order to create a viable plan of action to address this problem, the industry must take an extensive close examination into all aspects of pathophysiology of the disease process, epidemiological cost factors as well as the pharmacological agents.

Identifying the true indirect and direct cost of the various medications used in the market to treat type II is a crucial step in diabetes management (Caro et al., 2002). Revealing the cost savings and health benefits of the medications being prescribed allows the stakeholders to have a sense of clarity for the pharmaceutical agents ordered. The consequences of not understanding the causative factors associated with this chronic disorder, type II diabetes, is dangerously expensive (Boyle et al., 2010).

Cost effectiveness of treatments for type II diabetes and other chronic disorders is a major concern for America's economy. According to ADA (2018), the total cost of diabetes continues to escalate regardless of the new treatment modalities. Having a sense of clarity in terms of the indirect and direct cost of the treatment modalities for type II diabetes allows the stakeholders to make more informed choices (Bolen et al., 2007).

The *emergence of the hypotheses* identified in this study stemmed from the high cost of prescription medications to the American public, government, employers and health insurance companies. When viewed in isolation, the direct cost of prescription medications can seem quite expensive. However, a broader view of the cost of medications, which include:

- Cost of complications avoided due to the use of specific medications
- Hospitalization cost avoided due to the use of specific medications
- Emergency Department visits avoided due to the use of specific medications
- Prevention of complications due to the use of specific medications

can provide greater clarity concerning data based evidence in the assessment of the true cost of medication therapy (Herman, 2011). This doctoral thesis examined the direct and indirect cost of medications used to treat type II diabetes using a broader view of the actual cost of these medications. The aforementioned studies demonstrate the importance of health impact assessments on implementing change within an industry.

2.7 Hypotheses

The general null hypothesis for this action learning based study was created through the processes identified in the theoretical framework of creating a ”*knowing organization*” via the links of sense making, knowledge creating and decision making. The null hypothesis was there is not a correlation between health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. The data gathered from this action learning based study was to assess the following hypotheses:

1. There are no more cardiovascular events resulting in cardiovascular rehabilitation in type II diabetic persons in Georgia prescribed combination generic medications for type II diabetes than persons prescribed monotherapy generic agents and non-generic agents for type II diabetes.

2. There are no more renal insufficiency episodes resulting in dialysis treatments in type II diabetic persons in Georgia prescribed generic medications (both monotherapy and combination) for type II diabetes than persons prescribed non-generic medications for type II diabetes.

3. There are no more amputations experienced in type II diabetic persons in Georgia prescribed generic medications (both monotherapy and combination) for type II diabetes than persons prescribed non-generic agents for type II diabetes.

4. There are no more cancer episodes experienced in type II diabetic persons in Georgia prescribed generic (combination) medications and DPP4 inhibitors for Type II diabetes than persons prescribed (monotherapy) non-generic agents.

5. There are no differences in the absenteeism rate of type II diabetic persons in the work force in Georgia; regardless, of the pharmacological treatments prescribed for type II diabetes.

6. There are no differences in weight gain in type II diabetic persons in Georgia; regardless, of the pharmacological treatment prescribed

7. There are no differences in the overall level of satisfaction of prescribed treatment of choice for type II diabetic persons in Georgia.

CHAPTER 3: METHODOLOGY

3.1 Introduction

Chapter 3 consists of information gathered to characterize the type II diabetes population in Georgia, USA. It involves a description of the subject population and research sampling, research setting, ethical considerateness and research design. The research instrument utilized in the study, techniques concerning the data collection, data recordings and an analysis have been explained.

The purpose of the research study was to compare the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. A questionnaire implemented in this study was developed to determine the health benefits and cost savings of diabetes medications used to treat type II diabetes.

3.2 Research Setting

The setting for the study was various diabetes support groups in Georgia. These diabetes support groups are managed by clinic directors. The clinic directors granted permission to obtain consent and distribute the instrument to the study participants. The economy of these various research settings cities in Georgia were mainly agricultural business and manufacturing.

3.3 Population and Sampling

The population for this action learning based research was comprised of persons over the age of 18 with a diagnosis of type II diabetes and was presently prescribed at least one FDA approved medication for diabetes. The study participants' revealed

their information voluntarily. Those study participants, who met the criteria, were provided with a copy of their rights and the consent forms were signed accordingly. This research population was considered a purposive controlled sample used to identify the overall fiduciary impact of the pharmaceutical choices used to treat type II diabetes in the state of Georgia (Easterby-Smith et al., 2008 p. 218). The participants were chosen from those persons diagnosed with type II diabetes who attended diabetes support group meetings in Georgia, United States. The following indicators were specific criteria for subject selection: adult over the age of 18; able to read, write and comprehend the English language; have a diagnosis of type II diabetes; presently have a prescribed treatment regimen of at least one FDA approved medication for type II diabetes; not be hearing impaired and able to remain seated for at least 15 minutes.

Three hundred and one subjects meet the criteria for this action learning based research study. Three hundred and one subjects participated in the research study primarily because of the purposive controlled sample group and the fact that the clinic directors had provided permission for the investigator's presence in the facility (Leedy & Ormrod, 2005).

3.4 Ethical Considerateness

Permission to conduct the study was acquired from the Committee on Research Ethics (Health and Human Subjects Committee) of the University of Liverpool. The clinic directors of identified diabetes treatment centers participating in the study provided written consent as well (Appendix A). The participants, who met identified criteria for inclusion in the study, were provided information about the study

(Appendix B). These individuals were requested to authorize consent to participate in the study by signing an actual consent form (Appendix C).

3.5 Research Design

This action learning based research implemented a simple ex post facto design. This design was chosen to be assured that a complete and factual comparison of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. The independent variable, medications used to treat type II diabetes, was present prior to this study; therefore, this study is considered a simple ex post facto design (Leedy & Ormrod, 2005). The study participants were not randomly assigned to a treatment condition because all participants were indeed diagnosed type II diabetic subjects. However, the investigator did manipulate the categorization of the responses as it related to the independent variable identified by the study participant. This manipulation of the categorization of the independent variable(s) allowed the researcher to determine the relevant response as it relates to the dependent variables, which have been identified as cost and health benefits of the medications used to treat type II diabetes. The responses were examined by the investigator. A comparison of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America was then determined via statistical analysis.

3.6 Research Instrument

The demographic questionnaire and investigative questions were created based upon the guiding inquiries of the study and the literature reviewed. The investigator

explored various healthcare journals, managed care journals, interviews imploring mixed methodologies and data analysis techniques (Herr & Anderson, 2005; Boyd, 2002; Raelin, 2003; Leedy & Ormrod, 2005; Choo, 2006). Using the concepts identified in the theoretical framework of the Knowing Organization (Choo, 2006), the questions were created. According to Choo (2006 p. 230), in sense-making when attempting to access information during the process of *information needs*, clarity is crucial. Conflicting interpretations and meanings should be avoided. In the process of *information seeking*, accessing the channels of communication may influence the information seeking behavior. In the process of *information use*, information can be shaped by cognitive schemas of the various stakeholders – including the investigator. The data driven instrument used to collect the data was established (Appendix D). The first three questions of the study dealt with the demographics of the study participants. The fourth question dealt with the duration in which the study participant had been diagnosed with type II diabetes. The fifth question revealed the identification of the type of medications that were being prescribed for the type II diabetic study participants. The sixth question revealed whether or not the study participants actually experienced any long term complications associated with type II diabetes. The seventh question revealed whether or not the study participant had gained any weight since he/she had been prescribed medications for type II diabetes. The eighth question revealed whether or not the study participant remained in the workplace and if so, an absenteeism rate was established. The ninth question revealed if the study participant had experienced any cancer episodes since he/she had been diagnosed and treated for type II diabetes. The tenth question revealed

whether or not the study participant was satisfied with his/her treatment regimen for type II diabetes.

The questionnaire was submitted to the dissertation committee and interview questions were revised as recommended. The questions were modified until they were easily comprehensible and capable of obtaining the participants' experience concerning their diabetes treatment regimen.

3.7 Theoretical based data collection and recording

The following approach was used to collect and record data for this action learning research based study: The investigator reviewed the interview process with the participants before the actual interview was conducted. This step was implemented in order to minimize disruptions and to reassure the research participants of the confidentiality of the information provided during the interviews. Full consent was obtained from each participant prior to the actual interview. The participants were notified that each questionnaire was coded in an effort to maintain confidentiality. The alpha / numerical coding allowed the investigator to be the only person able to identify the study participant(s). With the implementation of this coding process, the participants' given names were not identified on the questionnaires or any meeting notes written by the investigator. The participant(s) was only referred to by the codes assigned by the investigator. Prior to the interview, each participant was provided with a copy of their rights as study participants. Leaving a copy with the study participant, the investigator obtained a signed copy of these rights from the participant(s) in an effort to verify participant comprehension. All research recorded notes as well as completed questionnaires remains properly

protected, secured and maintained by the investigator. The data for this investigative study was obtained through a semi-structured interview process of the chosen participants from the various diabetes support group meetings throughout the state of Georgia. The technique of semi-structured interviews was implemented in order to allow the investigator the liberty to elaborate on any of the participant responses if needed. The investigator referenced an interview guide from which the questions were properly structured (Boyd, 2002). Meeting notes were written per the investigator during the interview. The researcher adhered to the announced estimated time for each interview, which was 10-15 minutes. There were three hundred one (301) interviews conducted during the time frame of November, 2014 through January, 2015. Upon the completion of the interview process, the information was reviewed with the participant(s). The purpose of reviewing the information with the study participant is due to the fact that the implementation of the interview process is a part of knowledge sharing (Choo, 2006 p. 308). Choo (2006) identifies knowledge sharing as a norm that is reinforced through trust and reciprocity. Reviewing the gathered information for accuracy is a worthwhile gesture to reiterate the importance of this information concerning personal experiences and practices.

3.8 Data Analysis

In the action learning based research study, micro-costing was utilized to obtain information regarding direct medical costs (medication regimen, healthcare visits, long term complications associated with diabetes) as well as indirect medical costs (absenteeism rates) . Respectively, GoodRx, Inc. and CostHelper, Inc., were implemented to authenticate pricing used for medication(s) and healthcare services /

procedures. A statistical analysis was performed on the assembled data. The data was computed by using both inferential and descriptive statistics. Descriptive statistics were used as a method to calculate distributions of frequency and various numerical values. Inferential statistics were implemented for the chi-square test, which was applied to the 6x4 contingency table. The chi-square test was applied to the contingency table in order to assess the significance of the various outcomes identified within the study. The calculation of the chi-square statistic performed a comparison of frequencies. These frequencies can be identified as those observed during the data collection process and the expected outcomes if there was a null relationship between the variables. The identified outcomes were identified in the rows and columns of the contingency table.

A summarization of the calculated differences between the observed and expected frequencies for each section within the table was identified and documented. For this action learning based research study, a 6x4 contingency table was utilized. According to Leedy and Ormrod (2005 p. 274), chi-square is used to determine how closely observed frequencies and probabilities complement the expected frequencies or outcomes. Using chi-square as a nonparametric statistic, which is appropriate to compute this nominal data. The calculation of the degrees of freedom (df), is implemented to determine whether the null hypothesis can be rejected or not. It is based on the variables and the outcomes identified in the calculated data. According to Leedy and Ormrod (2005), P-value can be defined as a calculated probability. To further explain, it is determining the probability of a variate that would assume a value greater than or equal to the observed value strictly by chance.

3.9 Summary

Chapter 3 is a descriptive chapter used to identify the procedures for selecting the population for this study. The study participants were provided with information sheets explaining the purpose of the research and the importance of confidentiality. Before the questionnaires were distributed, written consent was obtained from each study participant.

This is an action learning based research study. The design used is known as a simple ex post facto design. The study participants (N=301) were adult persons diagnosed with type II diabetes who were presently on a treatment regimen of at least one FDA approved medication used to treat type II diabetes. The settings used for this study were various diabetes support group meetings across the state of Georgia, United States during the months of November, 2014 through January, 2015.

The instrument, consisting of ten (10) questions, was created from concepts derived the theoretical framework of the *Knowing Organization* (Choo, 2006). This instrument was administered by the investigator of the study. The responses from the instrument was used to compare the cost savings and health benefits of medications used to treat type II diabetes in the state of Georgia, United States. The instruments identified for collecting subject data and recording responses have been described in Chapter 3.

CHAPTER 4: DEMOGRAPHICS AND SENSE-MAKING OF THE RESULTS

4.1 Introduction

This study represented a demographical and geographical diverse population of type II diabetics in Georgia, United States. Inferences were made about the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. Chapter 4 represents an analysis of the overall results by identifying the demographics of the population of the study participants and the results of the data gathered from the participants. The aforementioned data has been respectively positioned at Section 1(Demographics of Sample Population) and Section 2 (Group Results) of Chapter 4.

4.2 Demographics of Sample Population

How old are you? Upon reviewing the ages of the study participants, the ages ranged from thirty seven to seventy eight. The categorization of the age ranges is identified in Table 1. See Table 1.

AGE	FREQUENCY	PERCENTAGE
30-39	28	9.30%
40-49	37	12.29%
50-59	112	37.20%
60-69	101	33.55%
70-79	23	7.64%

TOTAL	**301**	**100%**

TABLE 1: Age Ranges N = 301

Are you male or female? Eighty percent of the study participants who responded were female and twenty percent of the study participants were male. The gender proportions are shown in Table 2. See Table 2.

GENDER	FREQUENCY	PERCENTAGE
MALE	**61**	**20%**
FEMALE	**240**	**80%**
TOTAL	**301**	**100%**

TABLE 2: Gender N = 301

What is your race? The study participants revealed a mixture of various races throughout the state of Georgia. The racial demographics are identified in Table 3. See Table 3.

RACE	FREQUENCY	PERCENTAGE
Caucasian	**153**	**50.83%**
African American	**94**	**31.23%**
Hispanic	**44**	**14.61%**

Indian	**10**	**10%**
Total	**301**	**100%**

TABLE 3: Racial Demographics N = 301

4.3 Group Results

A Comparison Study of the Health Benefits and Cost Savings of Diabetes Medications Used to Treat Type II Diabetes in the State of Georgia, United States of America. The questionnaires were hand distributed and one hundred percent of the questionnaires were returned.

How long have you had type II diabetes? The duration in which the study participants had been diagnosed with type II diabetes varied a great deal – ranging from newly diagnosed (less than 6 months) to over twenty years. Table 4 indicates the duration in which the participants had been diagnosed with type II diabetes. See Table 4.

DURATION OF DIAGNOSIS (YRS)	FREQUENCY	PERCENTAGE
0-5	**84**	**27.90%**
6-10	**97**	**32.22%**
11-15	**02**	**0.66%**
16-20	**104**	**34.55%**
➢ **20**	**14**	**4.65%**

TOTAL	**301**	**100%**

TABLE 4: Duration of diagnosis (years) N = 301

Please list the current medications you are presently taking for diabetes. Upon gathering the data, the researcher coded the medications identified via using an alpha-numerical coding system signifying the medication class. The classes of medications identified in this study were as follows: secretagogues {sulfonylureas (SU)}, sensitizers {bigunides and thiazolidinediones (TZD)}, dipeptidyl peptidase-4 inhibitors (DPP4) and glucagon-like peptide receptor agonists (GLP-1). Many of these agents were prescribed in monotherapy as well as combination therapy. A categorization of the medication findings has been identified in Table 5.

See Table 5.

MEDICATION	**FREQUENCY**	**PERCENTAGE**
MONOTHERAPY		
Biguanide	**25**	**8.3%**
TZD	**23**	**7.64%**
DPP4 Inhibitor	**74**	**24.58%**
GLP1	**54**	**17.94%**
COMBINATION		
SU + Biguanide	**102**	**33.88%**
TZD +Biguanide	**23**	**16.61%**
TOTAL	**301**	**100%**

TABLE 5: Medications identified in the study N = 301

Have you experienced any of the following? The following conditions were listed in question six: stroke, heart attack, blindness, dialysis and amputation. The date of occurrence was identified to reveal if the condition was diagnosed before or after the diagnosis of type II diabetes. The findings regarding these complications associated with diabetes were identified in Table 6. See Table 6.

COMPLICATION	FREQUENCY	PERCENTAGE
Stroke		**3.65%**
Before diagnosis	**0**	
After diagnosis	**11**	
Heart Attack		**8.97%**
Before diagnosis	**2**	
After diagnosis	**25**	
Blindness	**0**	**0%**
Dialysis		**2.65%**
Before diagnosis	**0**	
After diagnosis	**8**	
Amputation		**1.32%**
Before diagnosis	**1**	
After diagnosis	**3**	
Non-Applicable	**251**	**83.38%**
Total	**301**	**100%**

TABLE 6: Complications associated with type II diabetes N = 301

Have you gained any weight since you have been taking medication(s) for diabetes? If so, how much have you gained? For simplicity, the responses to this question were integrated with the responses to the question regarding

medication identification. If applicable, the average weight gain for each category has been computed and indicated in the table. The findings to this question 7 can be identified in Table 7. See Table 7.

Meds & Weight Inquiry	FREQUENCY	PERCENTAGE
Monotherapy		
Biguanide	***25***	
Weight gain NO	**22**	**88%**
Weight gain YES	**3**	**12%**
How much gain?	**8#**	
TZD	***23***	
Weight gain NO	**4**	**17.39%**
Weight gain YES	**19**	**82.60%**
How much gain?	**22#**	
DPP4	***74***	
Weight gain NO	**68**	**91.89%**
Weight gain YES	**6**	**8.10%**
How much gain?	**7#**	
GLP1	***54***	
Weight gain NO	**50**	**92.59%**
Weight gain YES	**4**	**7.40%**
How much gain?	**6#**	
Combination		
SU + Biguanide	***102***	
Weight gain NO	**3**	**2.94%**
Weight gain YES	**99**	**97.05%**
How much gain?	**25#**	
TZD + Biguanide	***23***	
Weight gain NO	**2**	**8.69%**
Weight gain YES	**21**	**91.30%**

How much gain?	**25#**	
TOTAL	***301***	

TABLE 7: Weight gain in conjunction with treatment N = 301

Are you still active in the work force? If so, how many days have you had to "call in sick" due to your diabetes? This question pertains to the absenteeism rates relating to type II diabetes. Table 8a and 8b reveal the findings of the study participants' employment status and their rates of absenteeism (categorized via age) respectively. See Tables 8a and 8b.

Employment Status	**FREQUENCY**	**PERCENTAGE**
Unemployed	**53**	**17.60%**
Employed	**248**	**82.39%**
Days Absent	**150**	
Total	**301**	**100%**

TABLE 8A: Employment Status with overall absenteeism rating N = 301

Absenteeism Rates	**FREQUENCY**
Age: 30-39	**28**
unemployed	**0**
employed	**28**
Absent from work	***12 days (average)***
Age: 40-49	**37**
unemployed	**0**
employed	**24**
Absent from work	***24 days (average)***

Age: 50-59	**112**
unemployed	**0**
employed	**112**
Absent from work	***54 days (average)***
Age: 60-69	**101**
unemployed	**29**
employed	**72**
Absent from work	***60 days (average)***
Age 70-79	**23**
unemployed	**23**
employed	**0**
Absent from work	***N/A***
Total	**N = 301**

TABLE 8B: Employment Status with absenteeism rating according to age N=301

Have you been diagnosed with cancer since you have been diagnosed with diabetes? If so, where was the cancer and when was the date of occurrence?

The findings revealed four percent (4%) of the study participants had been diagnosed with (various) cancers. Seventy five percent (75%) of these cancer diagnoses occurred after the patient had been diagnosed with type II diabetes. Table 9 depicts these findings. See Table 9.

Cancer Diagnosis	FREQUENCY	PERCENTAGE
No	**289**	**96.01%**
Yes	**12**	**3.98%**
Types of Cancer		
Breast	**2**	
Before diagnosis	**0**	
After diagnosis	**2**	
Colon	**4**	
Before diagnosis	**0**	

After diagnosis	**4**	
Liver	**3**	
Before diagnosis	**1**	
After diagnosis	**2**	
Pancreas	**3**	
Before diagnosis	**0**	
After diagnosis	**3**	
Total	**N = 301**	**100%**

TABLE 9: Categorized cancer diagnosis N = 301

Are you satisfied with your present treatment regimen for diabetes? The findings of this question identifies whether or not the study subjects are satisfied with their present treatment for diabetes management. These findings are reflected in Table 10. See Table 10.

Response	FREQUENCY	PERCENTAGE
Yes	**187**	**62.12%**
No	**114**	**37.87**
Total	**301**	**100%**

TABLE 10: Treatment regimen satisfaction N = 301

CHAPTER 5: EVALUATION OF OUTCOMES

5.1 Introduction

The collected data related to the direct and indirect cost of diabetes were statistically analyzed using inferential and descriptive statistics. Inferential statistics used the chi-square test which was applied to the 6 x 4 contingency table. Descriptive statistics employed were response rates, frequency distributions, numerical values identifying calculated responses pertaining to the pharmaceutical agents and comorbidities (relating to diabetes) identified in the interview process. The qualitative analysis portion of the study demonstrated that the responses of the research subjects were multifaceted and complex. The responses to the questionnaires were analyzed using the chi-square test within a 6 x 4 contingency table to compute the significance of the comparison. This analysis also indicated that there are strong correlations relating to the disease process of diabetes and certain long term complications as it is related to cost. The similar themes that materialized throughout these responses reiterated the challenges that individuals who have been diagnosed with type II diabetes struggle with in regards to their well-being on a daily basis (Gray et al., 2000).

5.2 Research Question Outcomes

The first three questions of this study dealt with demographics. The first question revealed that within this study group of participants the ages ranged from thirty seven

to seventy eight years of age. The majority of the participants were of female (80%) and Caucasian (50.83%).

The fourth question dealt with the duration of which the participant had been diagnosed with type II diabetes. The durations varied with this study group. In this action learning process, recognizing the duration of the illness was beneficial as it corresponds with the pharmacological therapies provided and the overall cost of treatment. The participants ranged from being newly diagnosed to a time of diagnosis of over twenty years. The duration of diagnosis group in the 16-20 year range was identified as the most prominent group with a rate of 34.55%; whereas, the group ranging from 11-15 years was least represented at 0.66%.

The fifth question revealed the identification of the type of medications that were being prescribed for these type II diabetic participants. Upon cross-referencing the data, this investigator discovered that there was a correlation in the types of medications being prescribed to certain age groups of study participants. This study revealed that those study participants who were eligible for Medicare Part D, age 65 and older, were being prescribed medications in three primary categories – sulfonylureas, thiazolidinediones and biguanides. These medications were either ordered as monotherapy or in combination therapy with each other. Those participants who were under the age of 65 and who remained in the workforce with commercial insurance were prescribed medications in three primary categories as well – biguanides, DPP4-inhibitors and GLP1 receptor agonists. Either the DPP4 inhibitor or GLP1 receptor agonist would be ordered as monotherapy or in conjunction with a biguanide.

The sixth question revealed whether or not the study participants experienced any long-term complications associated with diabetes such as stroke, heart attack, blindness, (end stage renal disease resulting in) dialysis or amputation. The date of occurrence was identified to determine if the participant experienced the incident before or after the type II diabetes diagnosis. This study revealed that 16.62% of the participants experienced complications identified in the questionnaire. Of this 16.62%, 94% of these participants experienced these complications after they had been diagnosed with type II diabetes. Two of the participants experienced heart attacks before they were diagnosed. One of the participants experienced a 'blood clot' after a surgical procedure, which resulted in a heart attack. The other participant was diagnosed with coronary heart disease and had a heart attack two years before being diagnosed with type II diabetes. The participant that revealed the BKA (below the amputation) which occurred before the type II diabetes diagnosis disclosed that this amputation was due to trauma (car accident).

The seventh question revealed whether or not the participants have gained weight since he/she has been taking medication(s) for type II diabetes. The study results substantiated information noted within the literature regarding the medications used for diabetes and their association with weight gain. The participants taking agents within the categories of sulfonylureas and thiazolidinediones revealed the most weight gain albeit in monotherapy or combination therapy. The Medicare eligible age group of 65 and older as previously mentioned is being prescribed this category of agents more often than other age groups within this study.

The eighth question dealt with whether or not the study participant remained in the workforce and if so had he/she ever had to “call in sick” (within the past year) due to a clinical complication associated with type II diabetes. The information regarding absenteeism and age was cross-referenced. The study revealed that after the age of fifty the rates of absenteeism actually more than doubled for those participants who remained in the workforce.

The ninth question revealed whether or not the study participant had been diagnosed with cancer of any kind and if so, did the diagnosis occur before or after the diagnosis of type II diabetes. Four (4) percent of the study population had indeed been diagnosed with (various) cancers. Of this four (4) percent, one of the participants revealed being diagnosed with liver cancer before he was diagnosed with type II diabetes. The participant revealed that the liver cancer was detected after many years of being diagnosed with Hepatitis C. This was (an undetermined amount of years) before the type II diabetes diagnosis. On the other hand, seventy five (75) percent of the participants were indeed diagnosed with various cancers – after the type II diabetes diagnosis. The cancers identified in this study were as follow: breast, colon, liver and pancreas.

The tenth question revealed whether or not the study participants were satisfied with their present treatment for diabetes management. The majority (62.12%) of the participants were satisfied with their present treatment regimen. During the interview process, many of the participants admitted to experiencing side effects from the medication; however, still revealed that they were satisfied with the present regimen due to affordability of the treatment.

5.3 Discussion of the cost savings and health benefits of these findings

Micro-costing was used as a method to determine the cost savings and health benefits of the reported findings. Micro-costing can be defined as a cost estimation method, which permits a detailed assessment of reported healthcare costs, albeit direct or indirect (Frick, 2009; Smith, 2003). GoodRx, Inc., a private company not sponsored or affiliated with any pharmaceutical company, was implemented to identify pricing of medications reported by study participants. CostHelper, Inc. a privately owned company not affiliated with any particular healthcare company was used to provide information regarding the cost of the various healthcare services and procedures reported by study participants. These unitary costs for the medications, healthcare services and procedures were estimated utilizing this micro-costing technique. The computed nominal figure was then divided by the number of participants according to the category of medication identified on the instrument, generic or non-generic. Participants in the generic medication group were identified as those prescribed a biguanide (Metformin), thiazolidinedione (TZD), TZD + Met combo (combination of thiazolidinedione and Metformin), SU + Met (combination of sulfonylurea and Metformin) because these medications were listed as generic by the FDA at the time of this study (Hodgson & Kizior, 2014) . Participants in the non-generic mediation group were identified as those prescribed a DPP4 inhibitor or a GLP1 agonist because these medications were considered non-generic, according to the FDA, at the time of this study (Hodgson & Kizior, 2014).

The mean annual costs of the pharmaceutical treatments, healthcare services / procedures as well as absenteeism rates identified in this study are outlined in detailed

with a summation to follow. The tabulated costs of the overall treatment, direct and indirect, were divided by the number of study participants in each category of treatment. The cost savings and health benefits of the study participants prescribed generic versus non-generic were computed and identified. The total, direct and indirect, cost of the group taking generic medications was $149,382.23. The total, direct and indirect, cost of the group taking non-generic medications was $25,070. 54. A summation of the findings can be reviewed in Table 11.

5.4 Pharmacological Treatment: MET (Monotherapy treatment of Metformin)

In this study, twenty five participants had been prescribed Metformin (monotherapy) as the treatment of choice for type II diabetes. This medication is in the biguanide category. The average annual cost of healthcare provider services for this group of patients was $2,047.00 per person. This medication, generic at the implementation of this study, carried a nominal value of $96.00 per year (per person). There were no reported cardiovascular events resulting in cardiac rehabilitation for this group of study participants. There was one reported case of an amputation. The average cost to this amputation was $50,000. There were three reported cases of hemodialysis, commonly known as kidney dialysis, which had an average cost of $72,000 per episode. There were no cancer treatments reported in this group. The absenteeism rate for the Metformin group of participants computed an annual average of $654.00 per person. The monotherapy group of Metformin participants reported less weight gain than when used in combination therapy with other oral agents. Eighty-eight percent of the patients denied gaining weight with this therapy. Of the

twelve percent of the patients who admitted to gaining weight, the average weight gain was approximately eight pounds within a year.

Within this group of participants, the cost associated with the treatment of (monotherapy) Metformin is as follows:

- Quarterly physician appointments with the healthcare provider (2027 x 25) $51,175.
- Cost of medication used to treat type II diabetes (96x25) $2400.
- Cardiac Rehabilitation (0)
- Dialysis ($72,000 x 3) $216,000
- Amputation ($50,000 x 1) $50,000
- Cancer Treatments (0)
- Absenteeism Rate ($654 x25) $16,350.00

The total annual amount for the treatment of this (monotherapy) Metformin group of participants was $335,925.

5.4.1 Pharmacological Treatment: TZD (Monotherapy treatment of Thiazolidinedione)

In this study, twenty three participants had been prescribed a class of medication called Thiazolidinedione as a treatment of choice for type II diabetes. The average annual cost of healthcare provider services for this group of patients was $18,434.00 per person. This medication, generic at the implementation of this study, carried a nominal value of $624.00 per year (per person). There were three reported cardiovascular events resulting in cardiac rehabilitation for this group of study

participants. Each event averaged $89,676.00. There were no reported cases of an amputation in this group. There were two reported cases of hemodialysis, which had an average cost of $72,000 per episode. There was not any cancer treatments reported in this group. The absenteeism rate for the Thiazolidinedione group of participants computed an annual average of $1960.00 per person. This monotherapy group of the Thiazolidinedione participants reported a significant amount weight gain. In fact, 82.60% reported gaining an average of twenty-two pounds within a year.

Within this group of participants, the cost associated with the treatment of (monotherapy) Thiazolidinedione is as follows:

- Quarterly physician appointments with the healthcare provider (18,434 x 23) $423,982.
- Cost of medication used to treat type II diabetes (624 x 23) $14,352
- Cardiac Rehabilitation (89,767x3) $269,301
- Dialysis ($72,000 x 2) $144,000
- Amputation (0)
- Cancer Treatments (0)
- Absenteeism Rate ($1960 x 23) $45,080.00

The total annual amount for the treatment of this (monotherapy) group of Thiazolidinedione participants was $896,715.

5.4.2 Pharmacological Treatment: DPP4 (Dipeptidyl peptidase-4 inhibitor class)

In this study, seventy four participants had been prescribed a class of medication belonging to the dipeptidyl peptidase - 4 inhibitor class as a treatment of choice for type II diabetes. The average annual cost of healthcare provider services for this group of patients was $7409.00 per person. This medication, non-generic at the implementation of this study, carried a nominal value of $4147.00 per year (per person). There were two reported cardiovascular events resulting in cardiac rehabilitation for this group of study participants. Each event averaged $19,552.00. There were no reported cases of an amputation or dialysis in this group. There were four cases of cancers resulting in treatments for this group. The average cost of these treatments was $23,090 per person. The absenteeism rate for the DPP4 group of participants computed an annual average of $967.00 per person. The majority of the DPP4 group of participants did not report weight gain with their therapy. In fact, 91.89% denied gaining weight while on the medication. Only 8.10% of the participants admitted to gaining weight – averaging approximately seven pounds in a year.

Within this group of participants, the cost associated with the treatment of the DPP4 group is as follows:

- Quarterly physician appointments with the healthcare provider (7409 x 74) $548,266
- Cost of medication used to treat type II diabetes (4147 x74) $306,878
- Cardiac Rehabilitation (19,552 x 2) $39,104
- Dialysis (0)

- Amputation (0)
- Cancer Treatments (23,090 x 4) 92,360
- Absenteeism Rate ($967 x 74) $71,558.00

The total annual amount for the treatment of this group of DPP4 participants was $1,058,166.

5.4.3 Pharmacological Treatment: TZD + MET (combination treatment of thiazolidinedione + metformin)

In this study, twenty – three participants had been prescribed a combination medication with the ingredients of a thiazolidinedione and metformin for type II diabetes. The average annual cost of healthcare provider services for this group of patients was $12,044.00 per person. This medication, non-generic at the implementation of this study, carried a nominal value of $1626.00 per year (per person). There were ten reported cardiovascular events resulting in cardiac rehabilitation for this group of study participants. Each event averaged $81,934.00. There were two reported cases of an amputation in this group, which averaged $50,000 each. There were no reported cases of hemodialysis nor amputations within this group of participants. There were ten reported cases of cancer treatments reported in this group. These cancer treatments averaged $52,327.00 per episode. The absenteeism rate for this combination therapy of TZD /Metformin group of participants computed an annual average of $2300.00 per person. This group of participants reported a significant amount weight gain. In fact, 91.30% reported gaining an average of twenty-five pounds within a year.

Within this group of participants, the cost associated with the treatment of the thiazolidinedione + metformin combination therapy is as follows:

- Quarterly physician appointments with the healthcare provider (12,044 x 23) $277,012
- Cost of medication used to treat type II diabetes (1626 x 23) $37,398
- Cardiac Rehabilitation (81,934 x 10) $819,340
- Dialysis (0)
- Amputation (0)
- Cancer Treatments (52,327 x 10) $523,270
- Absenteeism Rate ($2300 x 23) $52,900

The total annual amount for the treatment of this combination therapy of thiazolidinedione + metformin was $1,711,920

5.4.4 Pharmacological Treatment: SU + MET (combination treatment of sulfonylurea + metformin)

In this study, one hundred two participants had been prescribed a combination medication with the ingredients of a sulfonylurea and metformin for type II diabetes. The average annual cost of healthcare provider services for this group of patients was $9302.00 per person. This medication, generic at the implementation of this study, carried a nominal value of $185.00 per year (per person). There were ten reported cardiovascular events resulting in cardiac rehabilitation for this group of study participants. Each event averaged $67,089.00. There were two reported cases of an

amputation in this group, which averaged $50,000 each. There were three reported cases of hemodialysis, which had an average cost of $72,000 per episode. There were four reported cases of cancer treatments reported in this group. These cancer treatments averaged $33,480 per episode. The absenteeism rate for this SU/Metformin group of participants computed an annual average of $2047.00 per person. This group of participants reported a significant amount weight gain. In fact, 97.05% reported gaining an average of twenty-five pounds within a year.

Within this group of participants, the cost associated with the treatment of the Metformin/sulfonylurea combination therapy is as follows:

- Quarterly physician appointments with the healthcare provider (9307 x 102) $949,314
- Cost of medication used to treat type II diabetes (185 x 102) $18,870
- Cardiac Rehabilitation (67,089 x 10) $670,890
- Dialysis ($72,000 x 3) $216,,000
- Amputation (50,000 x 2) $100,000
- Cancer Treatments (33,480 x 4) $133,920
- Absenteeism Rate ($2047 x 102) $208,794.00

The total annual amount for the treatment of this combination therapy of sulfonylurea +metformin participants was $2,297,686

5.4.5 Pharmacological Treatment: GLP1 (Glucagon like peptide -1 receptor agonist)

In this study, twenty seven participants had been prescribed a class of medication called Glucagon - like peptide -1 receptor agonists as a treatment of choice for type II diabetes. The average annual cost of healthcare provider services for this group of patients was $3,458.00 per person. This medication, non-generic at the implementation of this study, carried a nominal value of $6223.00 per year (per person). There were not any reported dialysis treatments, amputations, cancer nor cardiovascular events resulting in cardiac rehabilitation for this group of study participants. The absenteeism rate for the Glucagon – like peptide -1 receptor agonist group of participants computed an annual average of $1090.00 per person. This group of the Glucagon – like peptide -1 receptor agonist participants did not report a significant amount weight gain. In fact, 92.59% reported that they had not gained any weight while on this treatment.

Within this group of participants, the cost associated with the treatment of (monotherapy) glucagon – like peptide -1 receptor agonist is as follows:

- Quarterly physician appointments with the healthcare provider (3,458 x 54) $186,732.00
- Cost of medication used to treat type II diabetes (6223 x 54) $336,042.00
- Cardiac Rehabilitation (0)
- Dialysis (0)
- Amputation (0)

- Cancer Treatments (0)
- Absenteeism Rate (1090 x 54) $58,860.00

The total annual amount for the treatment of this group of Glucagon – like peptide -1 receptor agonist participants was $581,634.00.

5.5 Summation of direct and indirect cost

Medication Category	Annual Costs Direct & Indirect	Number of study subjects	Average Cost
Generic			
Metformin	**$335,925.00**	**25**	**$13,437.00**
TZD	**$896,715.00**	**23**	**$38,987.60**
TZD + MET	**$1,711,920.00**	**23**	**$74,431.30**
SU + MET	**$2,297,686.00**	**102**	**$22,526.33**
Non-Generic			
DPP4	**$1,058,166.00**	**74**	**$14,299.54**
GLP1	**$581,634.00**	**54**	**$10,771.00**
Total	**$6,882,046.00**	**301**	**$579,577.00**

Table 11: Summation of direct and indirect costs N = 301

5.5.1 Formula implemented

The formula implemented to define the chi-square was

$$X^2 = \Sigma_¡ \frac{(O_¡ - E_¡)^2}{E_¡}$$

Where $O_¡$ is the observed number of cases within the study who has a difference in the cost savings / health benefit whereas $E_¡$ is the expected number of cases to have a difference in the cost savings / health benefit. This chi square has been calculated by finding the variance between the observed versus the expected tabulated cases. The calculated variance is squared and divided by $E_¡$ within the equation. The value was tabulated

and this has been referred to as the chi-square value. This test of independence was instrumental in creating a greater level of accuracy in the cross classification summation. In the event that the null hypothesis is true, the observed and expected frequencies should be similar. In the event that the null hypothesis is not true, the observed and expected frequencies will not be similar. This sum is an indication to a greater observed frequency. This total was subtracted from the squared frequency of the expected value. In the event that the chi-square value is of a higher numerical value – then this serves as statistical evidence that the null hypothesis of independence should be rejected.

5.6 Tests of the Hypothesis

The hypotheses has been the base on which the statistical analysis has been presented. The following information presents each hypothesis with an independent analysis for each factor indicated in the data. Maximum acceptable significance level was $\alpha = .05$

Hypothesis 1: There are no more cardiovascular events resulting in cardiovascular rehabilitation in type II diabetic persons in Georgia who were prescribed combination generic medications for type II diabetes than persons prescribed monotherapy generic agents and non-generic agents for type II diabetes.

Oneway ANOVA (Table 12) reveals no significant difference in the number of cardiovascular events (strokes and heart attacks) experienced by persons in Georgia

between who were prescribed generic agents versus non-generic agents. Therefore, this null hypothesis cannot be rejected. This is interpreted to mean that the number of cardiovascular events (i.e., strokes and heart attacks) among persons taking generic medications for type II diabetes was statistically similar to the number of cardiovascular events among those taking non-generic medications for diabetes.

Table 12

One-way ANOVA of Cardiovascular Events

Source	*df*	SS	MS	*F*	*p*
Prescribed Generic	1.00	3.30	3.30	10.29	.185
Error	18.00	5.60	0.31	-	-
Total	19.00	8.80	-	-	-

Hypothesis 2: There are no more renal insufficiency episodes resulting in dialysis treatments in type II diabetic persons in Georgia who were prescribed generic medications (both monotherapy and combination) for type II diabetes than persons prescribed non-generic medications for type II diabetes.

Oneway ANOVA reveals no significant difference in the number of renal insufficiencies resulting in dialysis experienced by persons in Georgia who were prescribed generic medications versus non-generic medications for type II diabetes. Therefore, this null hypothesis cannot be rejected. This is interpreted to mean that the number of renal insufficiencies, which resulted in dialysis amongst persons taking generic medications for type II diabetes, was statistically similar to those prescribed non-generic medications for type II diabetes.

Table 13

One-Way ANOVA of Renal Insufficiencies Resulting in Dialysis

Source	*df*	SS	MS	*F*	*p*
Prescribed Generic	1.00	2.25	2.25	18.00	.160
Error	14.00	1.75	0.13	-	-
Total	15.00	4.00	-	-	-

Hypothesis 3: There are no more amputations experienced in type II diabetic persons in Georgia who were prescribed generic medications (both monotherapy and combination) for type II diabetes than persons prescribed non-generic agents for Type II diabetes.

Oneway ANOVA reveals no significant difference in the number of amputations experienced by persons in Georgia who were prescribed generic medications versus non-generic medications for type II diabetes. Therefore, this null hypothesis cannot be rejected. This is interpreted to mean that the number of amputations experienced by persons taking generic medications for type II diabetes was statistically similar to the number of amputations experienced by those prescribed non-generic medications for type II diabetes.

Table 14

One-Way ANOVA of Amputations

Source	*df*	SS	MS	*F*	*p*
Prescribed Generic	1.00	0.50	0.50	0.00	.40
Error	4.00	2.00	0.10	-	-
Total	5.00	2.50	-	-	-

Hypothesis 4: There are no more cancer episodes experienced in type II diabetic persons in Georgia who were prescribed generic (combination) medications and DPP4 inhibitors for type II diabetes than persons prescribed (monotherapy) generic agents.

Oneway ANOVA reveals no significant difference in the number of cancer episodes experienced by persons in Georgia who were prescribed generic medications versus non-generic medications for type II diabetes. Therefore, this null hypothesis cannot be rejected. This is interpreted to mean that the number of episodes of cancer experienced by persons taking generic medications in combination therapy for type II diabetes and DPP4 was statistically similar to the number of episodes of cancer by those prescribed other non-generic medications, such as GLP1, for type II diabetes.

Table 15

One-Way ANOVA of Cancer Episodes

Source	*df*	SS	MS	*F*	*p*
Prescribed Generic	1.00	5.00	5.00	50.00	.167
Error	18.00	1.80	0.10	-	-
Total	19.00	6.80	-	-	-

Hypothesis 5: There are no differences in the rate absenteeism of type II diabetics in the work force in Georgia regardless of the pharmacological treatments.

Oneway ANOVA reveals no significant difference in the absenteeism rate of type II diabetics in the work force in Georgia who were prescribed generic medications versus non-generic medications for type II diabetes. Therefore, this null hypothesis cannot be rejected. This is interpreted to mean that the absenteeism rate for persons taking generic medications type II diabetes was statistically similar to the absenteeism rate for those prescribed non-generic medications for type II diabetes.

Table 16

One-Way ANOVA of Absenteeism Rates

Source	*df*	SS	MS	*F*	*p*
Prescribed Generic	1.00	2131.60	213160	9.55	.173
Error	8.00	1786.00	1786.00	-	-
Total	9.00	3917.6	-	-	-

Hypothesis 6: There are no differences in weight gain in type II diabetics in Georgia regardless of the pharmacological treatment prescribed.

One-way ANOVA reveals no significant difference in episodes of weight gain experienced by persons in Georgia who were prescribed generic medications versus non-generic medications for type II diabetes. Therefore, this null hypothesis cannot be rejected. This is interpreted to mean that persons taking generic medications in type II diabetes experienced a similar amount of weight gain when compared to those prescribed non-generic medications.

Table 17

One-Way ANOVA of Weight Gain

Source	*df*	SS	MS	*F*	*p*
Prescribed Generic	1.00	1244.57	1244.57	1.92	.524
Error	12.00	7761.14	646.76	-	-
Total	13.00	9005.71	-	-	-

Hypothesis 7: There are no differences in the level of satisfaction with the prescribed treatment of choice for type II diabetes in Georgia regardless of the treatment regimen prescribed.

Oneway ANOVA reveals no significant difference in overall satisfaction level between prescribed treatment regimens for type II diabetic persons in Georgia. Therefore, this null hypothesis is not rejected. This is interpreted to mean that type II diabetic persons in Georgia taking generic medications and non-generic medications reported similar levels of satisfaction with their prescribed treatment regimen.

Table 18

One-Way ANOVA of Satisfaction Level of Treatment

Source	*df*	SS	MS	*F*	*p*
Prescribed Generic	1.00	1332.25	1332.25	0.11	.562
Error	2.00	25314.75	11991.25	-	-
Total	3.00	26647.00	-	-	-

5.6.1 NULL HYPOTHESIS

The null hypothesis was that there is not a correlation between health benefits and cost savings of diabetic medications used to treat type II diabetics in the state of Georgia, United States.

The results of this analysis were not statistically significant, $\chi^2(15) = 35.10$, $p > 05$. There is not a statistical significant relationship between health benefits and cost savings of diabetic medications used to treat type II diabetics in Georgia. Therefore, the null hypothesis cannot be rejected. Although an examination of the cross - classification matrix identified that more study participants prescribed non-generic medications experienced less direct and indirect cost to treat type II diabetes in Georgia, United States, the results were not statistically significant.

5.7 Summary

Chapter 5 represented a well-defined view of the demographics of this diverse population of participants in the study. The study participants' (N=301) responses from the research instrument revealed various themes concerning cost savings and health benefits of medications used to treat type II diabetic persons in Georgia, United States. The responses were statistically analyzed. The compiled data was analyzed to specifically test the null hypothesis identified in this study. $X^2 = 35.1$. The null hypothesis was not rejected.

The findings of this action learning based research study revealed that when compared there was not a statistical significance in the difference in the cost savings and health benefits of medications used in Georgia to treat diabetes.

CHAPTER 6: CONCLUSIONS, REFLECTIONS AND IMPLICATIONS

6.1 Introduction

The five preceding chapters of this action learning based study comprised of the aim of the study, a thorough review of the workplace problem, relevance and relativity components, hypothesis', literature review, theoretical framework specifics, procedural statistical and data analysis. Chapter 6 includes a conclusion and an overall summation of this action learning study.

6.2 Conclusion

This action learning based study was a purposive controlled study. The study participants included adult persons diagnosed with type II diabetes who were currently prescribed at least one FDA approved medication to treat type II diabetes. The aim of the study was to compare the cost savings to the health benefits of medications used to treat type II diabetes in Georgia, United States.

Consent was granted from the University of Liverpool's committee on research ethics, the clinic directors and the study participants. A questionnaire was distributed to each study participant who met criteria for inclusion into the study. The sample size of this study was three hundred one (n=301). Of the three hundred one questionnaires distributed, three hundred one were returned for a 100% response rate. The fact that this writer had obtained permission from the clinic directors in advance and consent for study participation was thoroughly reviewed before the questionnaires were personally distributed resulted in an enhanced response rate

(Boyd, 2002). The research instrument implemented to compare the cost savings and health benefits of medications used to treat type II diabetes in Georgia, United States was developed by the investigator.

A simple ex post facto design was used for this study. This type of design is often used in healthcare related research when a current therapy is already in place and one desires to investigate possible causal factors (Leedy and Ormond, 2005). This design was structured to compare the cost savings and health benefits of medications used to treat type II diabetes in Georgia, United States. The investigator manipulated the categorization of the independent variable(s) in order to properly determine the relevant responses as it related to the dependent variables, which have been identified as cost and health benefits of the medications used to treat type II diabetes. In an effort to summarize the differences amongst the observed and expected frequencies a chi-square test was implemented. When the data was analyzed, the results did not reveal a statistically significant difference in the cost savings and health benefits of medications used to treat type II diabetes in Georgia, United States.

It was hypothesized that there would be no difference at the .005 level of significance in the cost savings or health benefits of study participants regardless of the type of FDA approved medication(s) prescribed to treat type II diabetes. The level of significance criteria for the study was not surpassed. The null hypothesis was accepted. The null hypothesis revealed that, when compared, there was not a statistically significant difference in the cost savings and health benefits of FDA approved medication(s) prescribed to treat type II diabetes. The .050 level of

significance can be interpreted as a probability of five out of one hundred chances that the probability of this result may perhaps have occurred by random chance.

6.3 Summation

Data obtained from the study participants of this action learning based research did not reveal a statistical significance in the difference in the cost savings and health benefits of medications prescribed to treat type II diabetes in the state of Georgia, United States. The study subjects were active participants in various diabetes support group meetings in Georgia, therefore findings are not generalized. The findings of this action learning based research does however support previous literary works cited concerning the advancements of newly manufactured pharmaceutical agents used to treat type II diabetes. This data driven study is indicative that the newer pharmaceutical agents, also referred to as non-generic medications, created through research and development to treat type II diabetes are indeed more costly at their base prices; however, health benefits outweigh the cost of the adverse events as compared to the generic medications (Skidmore-Roth, 2015). The generic medications designed to treat type II diabetes are actually less expensive; however, there are hidden costs such as weight gain (Skidmore-Roth, 2015).

When this "hidden cost" of weight gain transitions into obesity, studies indicate a number of weight-related comorbid conditions that affect the cardiovascular system as well as the overall quality of life for the consumer (Apovian, 2013). Stakeholders within the industry, i.e. healthcare providers, managed care officials and pharmaceutical companies, have a common interest as it relates to therapeutic

regimen for type II diabetes. This common interest is cost. Creating a *knowing organization* has allowed this writer to appeal to the stakeholders as it relates to a treatment regimen. Treatment regimens chosen to treat type II diabetes that decreases the chances of weight gain and weight related comorbid conditions are available. Efficacy and cost-effectiveness are two of the most sought after components when choosing therapeutic agents to treat type II diabetes. To the healthcare provider, it is important because in the aspect of value-based medicine, the healthcare provider is often incentivized to treat the patient with the most economical treatment regimen available in order to "save money". The managed care officials within the insurance industry recognize that there are a number of treatment regimens available and profit is determined by contract acquisition. The pharmaceutical industry considers this important as well. This is proven with the value demonstrated as the research and development department of the pharmaceutical industry brings these products to market.

As these treatment regimens for type II diabetes are implemented in the patient's plan of care, the literature reflects that the stakeholders should be held accountable (Kerr and Hayward, 2013). The implementation of value-based medicine seems to hold all entities responsible as it links the reimbursement rates of the pharmaceutical company to the results associated with the therapy received. A contract is created and presented to the managed care providers (insurance companies) as well as the pharmaceutical company as a detailed proposal as to instructions on they will be reimbursed as it relates to patient outcomes-based data. The pharmaceutical company, such as NovoNordisk, Inc. would be required to present evidenced-based

data to illustrate that the expected hemoglobin A1C is in line with the standards of care presented by the American Diabetes Association. If such goals are not reached as indicated in the contract as outlined, the pharmaceutical company would be required to pay a “rebate” to the managed care company. According to the American Diabetes Association (2019), type II diabetes is a chronic illness that is creating a financial burden within the healthcare system in America. Due to the economic burden that this disease is inflicting on America, value-based contracting would be a fitting business-related approach to address the issue.

CHAPTER 7: IMPLICATION FOR KNOWLEDGE AND PRACTICE

7.1 Relating the findings to knowledge and practice

The findings of this action learning based research study indicate that stakeholders within the pharmaceutical industry can collaborate across company lines in order to create a *knowing organization – through sense making, knowledge creation and decision making.* One that recognizes the importance of full disclosure as it relates to treatment regimens for the type II diabetic persons is of utmost importance. Adverse events, such as weight gain, associated with older treatment regimens used to treat diabetes is a key factor in the overall cost of this chronic disorder. Diabetes, primarily type II diabetes, is costing North America millions of dollars each year (Rowley & Bezold, 2012; American Diabetes Association, 2019). In fact, Rowley and Bezold (2012) reveal that the statistics demonstrate an increase by 64% within the next decade. Discovering the impact of diabetes and the complications associated with this disease is a core defense in creating a viable solution to the dilemma. Americans are at an increased risk of developing this disease due to an aging population of people, familial history, smoking, lack of exercise and poor eating habits (Kim, 2007). The literature reveals that obesity is often identified as a common denominator in complications associated with diabetes such as cardiovascular disease, renal insufficiency, damaged eye vessels and nerve ending abnormalities (Brown et al., 1999; Caro et al., 2002). In fact, Fitch et al. (2017) reveals that those persons diagnosed with type II diabetes (compared to the non-diabetic population) are two to four times

more likely to have their cardiovascular systems compromised resulting in myocardial infarctions (heart attacks) and cardiovascular accidents (strokes). Statistics reveal that the population of type II diabetic persons also have an admission rate nine times higher for heart failure and five times higher for coronary revascularization procedures (Fitch et al., 2017). According to the Georgia based organization, Centers for Disease Control and Prevention (2012; 2017), these complications are creating a cumbersome burden on the economy in Georgia. The literature lacks evidence concerning the health benefits and cost savings of medications used to treat type II diabetes in Georgia. This action learning based research has revealed evidence to support that even though more sophisticated pharmacological agents have been developed through research and development, older treatment regimens continue to dominate the industry. Certain treatment options, namely generic pharmacologic treatments, are less expensive at the counter. This study reveals that the adverse events associated with these agents create a number of long-term expenses. The findings in this study indicated that these expenses were not proven to be statistically significant; however, numerous studies in the literature review reveal these clinically related long term expenses are significant not only to the patient but the healthcare industry as a whole (Lincoff, 2007; Powers, 2005; Skidmore-Roth, 2015; Wanner, et al., 2016) . According to Leedy and Ormrod (2005), the small sample size of this writer's study could have been a determining factor in the computed data resulting in a statistical insignificant finding.

With the exception of Metformin, weight gain has proven to be an adverse event of generic agents used in this study. Using the Tree Age Pro Software (Williamstown, Massachusetts), the Markov Model was implemented to identify a true comparison of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. Upon completion of this local comparison study, this writer was able to recognize the need to address the health benefits and cost savings of the higher priced prescription drugs used to treat type II diabetes by implementing the *Choo's knowing organization*. Through the components of *Choo's knowing organization* (sense-making, knowledge creation and decision-making) and the decision-making theory of Herbert Simon, *Bounded Rationality Theory*, this writer has been able to create actionable knowledge as follows:

- " make sense" of our current healthcare crisis
- create knowledge from data driven evidence in the form of an algorithm and value-based contract formation for the healthcare industry
- decision- making via recommending an avenue in which to compute the findings to assess the true value of the prescription therapy used to treat this chronic disease, type II diabetes.

7.1.2 Actionable Knowledge ~ Sense-making

Over eighty percent of the type II diabetic population in America are over – weight (Jacob et al., 2007). As this over-weight status transitions into obesity, a various number of health related risks emerge in the human body. Statistics

indicate that a modest decrease in weight, even five to ten percent, is associated with not only improved blood sugar levels but other weight related comorbidities as well (Cawley and Mayerhoefer, 2012). In particular, those disorders associated with cardiovascular conditions such as non-HDL cholesterol, systolic and diastolic blood pressure and triglycerides are improved. The treatment options for type II diabetes that are weight neutral (or may even promote weight loss) and will not pose an increase in major cardiovascular events (MACE) are considered desirable therapies according to the American College of Cardiology (ACC) (Fitch et al., 2017). To further explain, the treatment of diabetes was centered around normalizing blood glucose levels for many years. As the treatments for type II diabetes have evolved, a number of discoveries have been revealed throughout the years. Discoveries such as weight gain, weight-related comorbid conditions and overall effects associated with these discoveries. The research and development departments within the pharmaceutical companies, namely Boehringer Ingelheim and NovoNordisk have created a couple of classes of medications used to treat type II diabetes that have been statistically proven to reduce the risk of cardiovascular deaths. These recent developments in treatment, SGLT2 inhibitors and GLP1 receptor agonists (Empagliflozin and Liraglutide respectively), demonstrate not only glucose lowering properties but improved cardiovascular effects as well (Das et al., 2018). As mentioned in Chapter 2, there are meticulously organized clinical trials by both Boehringer Ingleheim and NovoNordisk that have proven to decrease the rates of myocardial infarctions, cardiovascular accidents and cardiovascular related deaths. In some instances,

patients undergoing treatment of SGLT2 inhibitors, there have been reductions noted in heart failure hospitalizations of those persons diagnosed with type II diabetes. It is important to note that these advantages were not related to the blood glucose levels.

7.1.3 Actionable Knowledge ~ Knowledge Creation ~ Algorithm

The American College of Cardiology recommends Empagliflozin or Liraglutide as first line treatment regimen in those type II diabetic patients who have been diagnosed with cardio-metabolic risk factors. Implementing the techniques of Simon's *Bounded Rationality Theory*, this writer has developed an algorithm that can be implemented by healthcare providers when considering treatment for type II diabetic patients who have been diagnosed with other cardio-metabolic risk factors (See Appendix E). This algorithm identifies an evidence-based approach to manage this particular population of type II diabetes in patients. To begin with, after being properly diagnosed, the patient is evaluated for either SGLT2 inhibitor or GLP1 receptor agonist therapy. There are three routes to consider. The first route examines the approach of a SGLT2 inhibitor. If the patient has experienced an allergic reaction to Empagliflozin, has severe renal impairment, end-stage renal disease or is presently undergoing dialysis, then this treatment is considered inappropriate. The second route examines the approach of a GLP1 receptor agonist. If the patient has a personal or familial history of Medullary Thyroid Carcinoma or Multiple Endocrine Neoplasia II, is pregnant or if the person has experienced an allergic reaction to the components of liraglutide then this

treatment is considered inappropriate. In both cases, if the therapy is prescribed and the patient is on another agent for diabetes, the dosage may need to be adjusted such as insulin or sulfonylurea. The adjustment may be necessary to prevent episodes of hypoglycemia. The third option is if the patient refuses treatment. If this is the case, the healthcare provider should counsel the patient on the consequences of not adhering to therapy and document accordingly.

This aforementioned algorithm may be used as a set of instructions created to guide the healthcare provider in aiding the type II diabetic patient to an optimal level of wellness. When the healthcare provider decides on the appropriate prescription medication, the second step is to create the value-based contract to make certain that the pharmaceutical company recognizes they will be held accountable for the claims concerning "better outcomes" than the older/cheaper medications used to treat type II diabetes.

7.1.4 Actionable Knowledge ~ Knowledge Creation ~ Value Based Contract

The purpose of creating a template for a value based contract is to allow the stakeholders within the healthcare industry (healthcare providers, managed care companies and pharmaceutical companies) to focus on a patient centric analysis of cost and benefit of the treatment regimen(s) chosen to treat type II diabetes. This template will allow the stakeholders to analyze the total cost of care for those type II diabetic persons who have been prescribed Liraglutide as opposed to those who have not been prescribed Liraglutide. Analyzing this data is critical because cardiovascular disease is the primary causative factor in not only disability but

death as well in the type II diabetic population. Creating value based contracts from this template allows managed care companies to negotiate with pharmaceutical companies in order to facilitate payment for quality care. The following is a template for the pharmaceutical company (namely NovoNordisk, Inc.) to create a value-based contract. This contract shall be created to improve the lives of those type II diabetic patients who have a risk of elevated blood sugars as well as an increased risk of cardiovascular disease. The following information serves as template for a value-based contract for the GLP1 receptor agonist, Liraglutide:

I. Develop a value-based medicine team to coordinate this venture. The team should consist of 6-8 participants with the following skill sets:

   Administrative staff with decision-making abilities shall be integrated to coordinate the efforts of others.

   Field staff that are able to communicate with the managed care companies and healthcare providers shall be integrated to be certain pertinent information is gathered appropriately.

   Staff from the department of commercial execution shall be integrated to analyze data appropriately. This portion of the team will be a part of the "checks and balance" portion of the process.

II. Create a value-based measurement plan that is congruent with the clinical studies outlined in the prescribed information.

Within 56 weeks of Liraglutide therapy, HbA1c will decrease by at least 1 – 1.5 points when compared to generic medications used to treat type II diabetes

Within 16 weeks of Liraglutide therapy, body weight will decrease by at least 4% when compared to generic medications used to treat type II diabetes

Within 56 weeks of Liraglutide therapy, statistical data will reveal less occurrences of cardiovascular deaths, nonfatal myocardial infarctions and nonfatal cardiovascular accidents when compared to generic medications used to treat type II diabetes

III. Upon completion of the value-based measurement plan of action, it is the recommendation of this writer that the committee shall present the proposal to the executive corporate team, including the CEO and CFO of NovoNordisk, Inc. Upon approval of the plan, it is recommended that the proposal shall be presented to the managed care companies who have decided to partner with NovoNordisk, Inc. Upon acceptance of this partnership, it is recommended that the desired outcomes derived from this partnership shall be communicated to the field staff. This proposal then recommends that the field staff communicate the partnership of this value-based medicine contract to the healthcare providers. Finally, this proposal recommends that a concerted effort shall be made to meet with those providers who are in network to provide care to the members with such contracted managed care plan.

7.1.5 Actionable Knowledge ~ Decision-making ~ Outcome measurements

This proposal of actionable knowledge shall be used to create a partnership with a value-based medicine committee within NovoNordisk and the managed care company. It is recommended that these stakeholders shall agree upon a third party corporation to gather the information with a definitive time frame to measure the outcomes. It is the recommendation of this writer that the company must be able to conduct thematic research implementing cloud computing in healthcare. It is recommended that the in order to capitalize on the ROI (return of investment) proper interpretation of the data is needed. If the goals are met, then the managed care company will be charged the full amount of the price of the GLP1 receptor agonist, Liraglutide. However, if the goals are not met, NovoNordisk shall provide a rebate, amount to be to be negotiated prior to contract development, to the managed care company.

Implementing Choo's Knowing Organization has allowed this writer to make sense of this work-place problem, create knowledge by developing an algorithm for type II diabetic patients who have been diagnosed with cardio-metabolic issues and a template for value-based medicine contract formation. Last but not least, the decision-making component has allowed this writer to implement a method of evaluation within outcome measurements.

7.2 Limitations

This data driven study has proven to be valuable and the research objectives were achieved; however, the following five (5) limitations are acknowledged and present the opportunity for further research as featured in section 7.3 below:

1. Primary dependence on the limited viewpoints of study participants: The study participants in this research consisted of a self-selected sample of type II diabetics in the state of Georgia from various diabetes support groups; therefore, the responses of these participants may not represent those of all individuals who have been diagnosed with type II diabetes in the state of Georgia. Generalization is limited. Sample size and diversity are both influential factors in research outcomes (Altman and Anderson, 2009; Leedy and Ormrod, 2005).
2. Limited knowledge of the variables associated with environmental, financial and social aspects of the study participants lives. Cranor et al, (2003) reveal a correlation between the environment, financial status and social variables as it relates to diabetes management.
3. The reliability and validity of the instrument was not tested : According to Coghlan and Brannick (2010) there are four areas in action research that are crucial in its success. These areas include participation, real life problems, joint meaning construction and workable outcomes. The information gathered is important to in order to capture components associated with the action learning process. According to Leedy and Ormrod (2005), an instrument tested for reliability and validity maximizes the chances of a more superior study.

4. Limited literature on developing tools to address issues within a restricted managed market. Herr and Anderson (2006) reveal the importance of being able to gather data to create knowledge albeit through concepts, personal experience, research or even intuition. Gathering the data is crucial in order to link it to theory development.
5. Attitudes of the professional personnel within in the diabetes treatment centers were not integrated as a variable. Attitudes of the personnel may influence the participants' responses. Keegan (2009) reveals that attitudes as well as knowledge created from experience can affect the approach, which in turn may affect the responses provided by the participants.

7.3 Recommendations for further research

Upon reflection of this action learning based research, recommendations are noted. These recommendations are as follows:

1. Diversify: This study should be extended to include the following: all types of diabetes i.e, type I diabetes, type II diabetes, gestational diabetes, and drug induced diabetes as well as diabetes 1.5, all FDA approved medications for type II diabetes (including insulin therapies)
2. Larger sample size: This study should be extended with a larger sample size in other facilities and other geographical locations as well
3. Cost Utility analysis tool: This study should be extended using another cost – utility analysis such as the Swedish Institute for Health Economics Cohort Model. According to Sonnenberg and Beck (1993), this model has been used

in other studies dealing with diabetes related issues and it also involves the use of a double Markov chain. This is important because a number of diabetic patients suffer with complications associated with obesity -which further complicates the health status of the participant.

4. Theoretical Framework: This study should be extended to include a different theoretical framework. These factors would alter the theoretical basis for this investigative study, which would make it an even more valuable source to the stakeholders in the industry (Van de Ven and Johnson, 2006).
5. Implementation of the newly developed Pay for Performance tool: This study should be extended implementing the outcomes data derived from the value-based medicine template developed by this researcher in order to determine the value of a particular medication used to treat diabetes.

7.4 My reflections on what I have learned:

I have learned that pharmaceutical agents being evaluated by the U.S. Food and Drug Administration (FDA) for treatment of type II diabetes are not only being evaluated for blood glucose regulation but cardiovascular safety as well (Smith, Goldfine and Hiatt, 2016). With this targeted approach, value-based medicine is becoming an essential component as managed care companies decide which medications to add to the formulary as a treatment regimen. Stakeholder involvement, albeit the managed care companies, healthcare providers or the pharmaceutical companies, will often identify pricing as a leading factor in the identification of the treatment regimen chosen for not only type II diabetes but other

chronic conditions as well (Fitch et al., 2017; Smith et al., 2016). This is impactful when viewed via a managerial perspective primarily due to the tremendous investment that the United States of America has in its healthcare system. The aforementioned stakeholders are searching for data – driven documentation in order to aid in excellent, cost-effective decision - making practices (Fitch et al., 2017; Sultz and Young, 2004). I have learned that this is crucial because outcomes - based data, as demonstrated in this doctoral dissertation, reveal authentic findings. These authentic findings uncover not only efficacy but safety of treatments implemented for chronic illnesses (Sultz and Young, 2004). As the healthcare industry evolves, identifying the health benefits as it relates to long term cost effectiveness improves the lives of those affected by chronic diseases by changing the behaviors of those creating the guidelines implemented to treat these chronic diseases such as type II diabetes and its culprit, cardiovascular disease (Kahn et al., 2008; Luce, 2005; Rosenthal et al, 2008).

Needless to say, the contents of this doctoral dissertation should be reviewed by all stakeholders within the healthcare industry. This information is especially crucial to those stakeholders who aim to seek a greater understanding in terms of the return on investment for pharmacological treatments used in diabetes management. There are a variety of stakeholders with whom I collaborate on a daily basis, such as employers, third party payers, healthcare professionals, consumers, managed care representatives, pharmacists, as well as other pharmaceutical sales professionals that will certainly find that this information is not only beneficial to patient care but a key component to managing the healthcare costs in America.

In practicality, if this study were to be reviewed by the stakeholders identified in healthcare such as healthcare professionals, managed care, pharmaceutical industries as well as the consumer – a profound impact on America's economy would be imminent. In addition, type II diabetes is a chronic disease that has been deemed treatable, not curable, at this point. After all, the greatest value of any data-driven study is determined by its ability to implement the model into the healthcare decision-making process (Edejer et al., 2003). Ultimately, altering the thought processes and behaviors of those making clinical decisions within the healthcare community is the key component to effective change. Yagudina et al., 2017 contends that stakeholders within the healthcare community are in need of data driven evidence, as indicated in this dissertation, in order to create a viable plan of care for the type II diabetic. This writer has created an algorithm and a template for generating a value-based medicine contract for the type II diabetic with a history of cardio-metabolic risk factors. These tools shall serve as a part of a solution to addressing the escalating cost associated with the treatment of the type II diabetic person living in the United States of America. As action learners, we must continue to create *knowing organizations* through sense making, knowledge creation and decision making in order to improve the lives of our fellow Americans. Due to the cost of healthcare in America, patient outcomes have become a profound influence on choices identified within the treatment regimen of those affected with a chronic disease, such as type II diabetes (Fagan et al., 2010). The stakeholders involved in caring for the American patient must realize that accountability is becoming more and more prominent in healthcare. Payers (managed care industry) and pharmaceutical companies must become partners

in order to address the escalating cost of healthcare in America. As a pharmaceutical sales consultant, I have implemented Choo's *Knowing Organization* and Simon's *Bounded Rationality Theory* to address my workplace problem by conducting this comparison study to aid in making sense of the problem, creating the algorithm and the template for creating a value-based contract and a method of evaluation of this contract. As a researcher, medical professional and consultant, I can honestly verbalize that I am a part of the solution to addressing one of the most complex problems in America, effectively treating the type II diabetic patient in America.

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APPENDICES

Appendix A

Mr. Sample Jones 01 November 2014
Clinical Director
Any Hospital
Any Address
Any Zip code

Re: Request for approval to distribute questionnaires to consumers within your facility

Dear Sir (or madam):

I have been actively pursuing my Doctorate of Business Administration degree from the University of Liverpool (United Kingdom) since Summer, 2010. The program requires a completion of nine (9) modules and a doctoral development plan in order to prepare one for the doctoral thesis. With the assistance of my supervisor, Dr. Joanna Poon, I have prepared a doctoral thesis proposal. This proposal was submitted in conjunction with the ethics application. I must obtain approval from you to interview participants from your facility in order to complete this investigative process. Please allow me to provide a brief overview of my intentions for the study. The title of my study is as follows: A comparison study of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America. The overall purpose of this study is to explore the health benefits and cost effectiveness of various medications used to treat type II diabetes in the state of Georgia, United States of America. A mixed methodology will be implemented in

order to complete this study. This mixed methodology will consist of both qualitative and a quantitative components. In the qualitative component of the study, an investigative tool in the form of a questionnaire will be implemented with the participants. In the quantitative component of the study, a clinical and cost analysis shall be conducted to determine the healthcare benefits and cost savings of the pharmaceutical agents used to treat diabetes in Georgia.

I have chosen to conduct this survey to those participants attending diabetes support group meetings because the meetings are pre-arranged, the audience is the appropriate population for this study and the meeting times are convenient for both the investigator and the participants. I need permission from you to administer the surveys in an effort to complete the qualitative portion of this methodology. The surveys will be hand delivered to the participants at your facility at an appointed group session time. In an event that the participant is not able to attend the scheduled meeting time, then the survey will be either emailed or faxed. Please note that the emails received are password protected and the fax machine is in a locked room in which only the investigator has a key to both methods of communication. These surveys shall be administered and collected within the months of November and December, 2014. Each survey will take approximately 10-15 minutes. These questions will be designed to gather information about the treatment regimen of diabetes, complications associated with this disorder and the cost analysis of the treatment regimen as it relates to the diabetes process.

I am presently employed as an executive diabetes care specialist with one of the largest manufacturers of diabetes products in the world. At this critical time of healthcare reform in the United States of America, it is of utmost importance to identify cost-effectiveness of agents for not only the patient but the national economy as well. The results of this study shall be beneficial for the consumer, healthcare providers as well as those decision-makers in the managed care markets.

Please contact me via the following method(s) of communication to either confirm or deny my request to implement this study with your facility: mobile (call or text messages accepted) 478.501.9253 or sonja.jenkins@onlineliverpool.ac.uk

Thanking you,

Sonja Jenkins

Appendix B

Committee on Research Ethics

Participant Information Sheet

You are being invited to participate in a comparative investigative study in Georgia. This study deals with the diabetes and the costs associated with this disorder. Your input is vital to the outcome of this study and your voluntary participation would be much appreciated. Please read this letter carefully and ask questions if needed. Your participation in this study is voluntary and your confidentiality is of utmost importance. You may withdraw from this study for any reason and at any time without fear of retaliation.

Title of Study: A comparison study of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America

Version Number and Date: 30 October 2014

Invitation: You are being invited to participate in a comparative investigative study in Georgia. This study deals with various treatments for diabetes and the costs associated with this disorder. Your input is vital to the outcome of this study and your voluntary participation would be much appreciated. Please read this letter carefully and ask any questions if needed. Your participation in this study is voluntary and your confidentiality is of utmost importance. You may withdraw from this study at any time.

What is the purpose of the study? The overall purpose of this investigative study is to discover and recognize the health benefits and cost savings of various medications used to treat type II diabetes in the state of Georgia. Due to the present epidemic status of diabetes in the United States, the information gathered will be of significance to the healthcare community within the state of Georgia as it relates to the creation of treatment protocols and policies for those consumers who have been diagnosed with type II diabetes.

Why have I been chosen to take part? You have been chosen to take part in this comparative investigative study because you are a type II diabetic who resides in Georgia, is over the age of 18, attends a support group for diabetes and is presently being treated with at least one medication indicated for use in type II diabetes.

Do I have to take part? Your participation in the study is voluntary and no, you do not have to take part in this investigative process. In fact, if you decide to participate

and later decide to withdraw – you may do so for any reason and at any time without fear of retaliation.

What will happen if I take part in the study? If you should decide to participate in this comparative investigative study, you will be provided with a questionnaire with a series of questions pertaining to your health and treatment modalities prescribed to treat your disorder (diabetes). This questionnaire is designed to gather information which will determine the overall cost of the disease process as it relates to medical treatment. The questionnaire shall take approximately 10-15 minutes to complete and shall be returned immediately upon completion to the student investigator, who shall be present at the support group meeting. If the questionnaire is electronically administered or faxed, the expected return time shall be within forty-eight (48) hours.

Expenses and / or payments: There will be no expense, compensation, gift(s) or payment to the participants of this study.

Are there any risks in taking part: There are not any physiological or financial risks associated in taking part in this investigative study. However, there is a minimal risk of one experiencing anxiety or a certain level of frustration/shame when revealing their health status and the prescribed treatment modalities for diabetes. This category of risk is considered psychological and has been anticipated to be minimal.

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Are there any benefits in taking part? There are benefits to you as a participant in this investigative process. The benefits include being a key player in generating knowledge regarding diabetes treatment and overall cost of therapy. This learning process is very important as it will provides information to be considered as managed care companies create policies for the upcoming healthcare reform.

What if I am unhappy or if there is a problem? In the event that a participant is unhappy and or there is a problem encountered within this investigative process, I can be notified immediately via telephone (4785019253) or email (sonja.jenkins@online.liverpool.ac.uk. If by chance the participant is not comfortable in contacting me then the Research Governance Officer can be contacted directly via the telephone at 1.612.312.1210 via email at liverpoolethics@ohecampus.com. If you choose to notified the University please provide the following information: title of study, researcher involved and the specifics of the complaint. As the researcher, I shall attempt to promptly rectify the problem to the best of my ability.

Will my participation be kept confidential? Yes. All documents shall be password protected via the computer and or locked securely in a cabinet whereas only the investigator has access.

What will happen to the results of the study? The results of this study shall be made available to further the education regarding diabetes and cost outcomes to anyone who has a desire to inquire.

What will happen if I want to stop taking part? Participants shall be allowed to withdraw for any reason and at any time without fear of retaliation.

Who can I contact if I have further questions? Please contact Sonja Jenkins at 4785019253 or sonja.jenkins@online.liverpool.ac.uk for further information.

Appendix C

Committee on Research Ethics

PARTICIPANT CONSENT FORM

Title of Research Project: A comparison study of the health benefits and cost savings of diabetes medications used to treat type II diabetes in the state of Georgia, United States of America

Researcher(s): Sonja Jenkins

The information you have submitted will be published as a report; please indicate whether you would like to receive a copy. ☐

I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications ☐

I agree for the data collected from me to be used in future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. ☐

I understand that I must not take part if I am deaf and not able to read the English language ☐

I agree for the data collected from me to be used in relevant future research. ☐

I understand that my responses will be kept strictly confidential. I give permission for members of the research team to have access to my anonymized responses. I understand that my alpha - numeric identifiers will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. ☐

I understand and agree that once I submit my data it will become anonymized and I will therefore no longer be able to withdraw my data.

Participant Name	Date	Signature
Name of Person taking consent	Date	Signature
Sonja Jenkins		
Researcher	Date	

Signature

Student Researcher:
Name: Sonja Jenkins
Work Address: Locust Grove, Ga 30248
Work Telephone: 4783659062
Work Email: Sonja.jenkins@ohecampus.com

Version 2.1
July 15, 2013

Appendix D

Questionnaire

Alpha / Numeric Identifier: _____ (to be completed by investigator)

1. How old are you? _____
2. Are you male or female? _____
3. What is your race? _____
4. How long have you had type II diabetes? _____
5. Please list the current medications you are presently taking for diabetes:

_____
_____
_____
_____
_____

6. Have you experienced any of the following? If so, please circle and identify a date of the occurrence.

Stroke date of occurrence:_____
Heart Attack date of occurrence:_____
Blindness date of occurrence:_____
Dialysis date of occurrence:_____
Amputation date of occurrence:_____

7. Have you gained any weight since you have been taking medication(s) for diabetes? _____ If so, how much have you gained? _____
8. Are you still active in the work force? _____If so, how many days have you had to "call in sick" due to your diabetes?_____
9. Have you been diagnosed with cancer since you have been diagnosed with diabetes? If so, where was the cancer _____ when was the date of occurrence?_____
10. Are you satisfied with your present treatment regimen for diabetes? _____

Appendix E : Approach to managing type II diabetic patients with cardiometabolic risk factors